Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *Track One Cases*	MDL NO. 2804 Civ. No. 1:17-md-02804-DAP HON. JUDGE DAN A. POLSTER

OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE

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I. INTRODUCTION

The Omnibus Memorandum Of Law In Support Of All Track One Bellwether Trial Defendants' Motions In Limine contains an overview of the controlling law governing motions in limine. AmerisourceBergen, Cardinal Health, McKesson, and Henry Schein (collectively, "Distributors") incorporate that discussion here.

II. IN LIMINE RULINGS REQUESTED

1. [D-1] The Court Should Preclude Plaintiffs From Offering Evidence Of, Or Arguments About, Distributors' Settlements With The DEA And West Virginia

Between 2007 and 2017, AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, and McKesson each entered into one or more settlement agreements with the U.S. Drug Enforcement Administration. They also entered into settlements with the State of West Virginia in 2017 and 2019. Throughout this litigation, Plaintiffs have repeatedly cited these civil and administrative settlement agreements as evidence that Distributors failed to comply with a purported duty to report and block suspicious orders and, as a consequence, Defendants are liable to Plaintiffs. The Court should exclude any evidence of, reference to, or arguments about these settlements because they are inadmissible under (1) Rule 408 of the Federal Rules of Evidence, which prohibits the use of settlement evidence to prove the validity of disputed claims, (2) Rules 401 and 402, because they irrelevant since they do not concern Distributor facilities that serviced Summit and Cuyahoga counties, and (3) Rule 403, because the any minimal probative value the settlements might have (and there is none) is far outweighed by the unfair prejudice that would result if the jury were exposed to these settlements.

Background. In every iteration of their Complaints, Plaintiffs allege that Distributors did not maintain effective controls against diversion in connection with their distribution of controlled substances to pharmacies in Cuyahoga and Summit counties. More recently, in their

Motion for Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under The Federal Controlled Substances Act (Dkt. No. 1910), Plaintiffs sought a ruling that Distributors violated certain duties under the Controlled Substances Act ("CSA") and implementing regulations—in particular, 21 C.F.R. § 1301.74—regarding suspicious order monitoring. *See* Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 2 (arguing that "[t]he Court can and should find, based on the undisputed evidence, that each of the Defendants repeatedly violated the Controlled Substances Act in their shipments to Summit and Cuyahoga Counties."). In support of that contention, Plaintiffs repeatedly cited Distributors' prior settlements with DEA. *See*, *e.g.*, Dkt. No. 1910-1 at 69-71, 81-82, 88, 93, 105-11, 113, 119-122.

Three of the six DEA settlements, however, contain no admissions of wrongdoing. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Three others contain narrow admissions that do not implicate the Track One Plaintiffs or their claims. In its 2012 Memorandum of Agreement (MoA), "Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." Dkt. No. 1960-103 (Ex. 209) at 3. The 2012 MoA does not identify what those failures were, when or where they occurred, or whether the inadequacies were violations of the CSA. In its 2017 Settlement, McKesson acknowledged that "at various times" from January 2009 to January 2017 "it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 8942(a)(5)." Dkt. No. 1964-24 (Ex. 236). None of the settlements has anything to do with distributions of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

The same is true of Cardinal Health's 2016 settlement with West Virginia, ABDC's 2017 settlement with West Virginia, and McKesson's 2019 settlement with West Virginia: they expressly disclaim any admission of wrongdoing.

The Settlements Are Inadmissible Under Rule 408. Admission of evidence or arguments about the settlements would contravene both the text and purpose of Rule 408, which "bars the admission of settlement agreements when offered 'to prove or disprove the validity or amount of a disputed claim.'" *United States v. Tevis*, 593 F. App'x 473, 476 (6th Cir. 2015) (quoting Fed. R. Evid. 408(a)(1) (evidence of "accepting . . . a valuable consideration in compromising . . . [a] claim" is "not admissible . . . to prove . . . the validity or amount of a disputed claim")); 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 408.03[5] (2d ed. 2017) ("Rule 408 applies . . . to completed compromises when offered against a compromiser."). "The purpose of this rule is to encourage settlements which would be discouraged if such evidence were admissible." Fed. R. Evid. 408 advisory committee notes, 1974 Enactment; *see Eid v. Saint-Gobain Abrasives, Inc.*, 377 F. App'x 438, 444 (6th Cir. 2010).

Under Rule 408, evidence of both the existence and content of prior settlement agreements is inadmissible for purposes of proving liability on a later civil claim. For example, in *Hobart Corporation v. Dayton Power & Light Co.*, No. 3:13-cv-115, 2017 WL 5956911 (S.D. Ohio Nov. 30, 2017), the court rejected plaintiffs' effort to establish that the defendant had assumed certain environmental liabilities because its corporate predecessor had made certain "admission[s]" in a settlement agreement resolving a separate case involving a different site. *Id.* at *19-20. Because the plaintiffs were "attempting to use evidence of a prior settlement agreement to establish . . . liability and prove the validity of a disputed . . . claim," the court held that the evidence was "inadmissible under Rule 408." *Id.* at *21. As the court explained,

"making the content of prior settlement agreements available for use in related litigation contravenes the very purpose of Rule 408." *Id.*

Likewise, in *Massachusetts Mutual Life Insurance Co. v. DLJ Mortgage Capital, Inc.*, 251 F. Supp. 3d 329 (D. Mass. 2017), the court precluded the plaintiff from relying on "certain facts set forth and acknowledged by Credit Suisse in a settlement agreement" with the Department of Justice to establish liability. *Id.* at 331. "[T]he letter, policy, and development of Rule 408" demonstrated that the DOJ settlement agreement, including the statement of facts expressly acknowledged by Credit Suisse therein, was "inadmissible" to establish liability. *Id.* at 332; *see also*, *e.g.*, *City of Mishawaka v. Uniroyal Holding, Inc.*, No. 3:04-cv-125, 2009 WL 499105, at *5 (N.D. Ind. Feb. 26, 2009) (rejecting plaintiff's attempt to use "prior settlement agreements" to "establish . . . liability by admission" because such a use of the agreements would be "precisely for the reasons prohibited by [Rule 408]").

Plaintiffs here clearly intend to rely on the settlements to prove Distributors' alleged failure to maintain adequate controls against diversion. *See*, *e.g.*, Plaintiffs' Mem. of Law (Dkt. No. 1910-1) at 20 (arguing that "a finding from this Court" that Distributors "shipped opioids in violation of the CSA has consequences for particular elements of many of Plaintiffs' claims"). Because the settlements represent the acceptance of a compromise of disputed claims, Plaintiffs' attempt to use the settlements to establish liability in the present cases is barred by Rule 408.[1] That is reason enough to bar any evidence of, reference to, or arguments about the settlements.

The Settlements Are Irrelevant Under Rules 401 And 402. The settlements also are irrelevant to Plaintiffs' claims and, therefore, are inadmissible under Rules 401 and 402. To

[1] Although Plaintiffs do not offer settlements for purposes of establishing the amount of damages they seek to recover, Rule 408 would bar their admission for that purpose as well. *See* Fed. R. Evid. 408(a)(1) (evidence of "accepting . . . a valuable consideration in compromising . . . [a] claim" is "not admissible . . . to prove . . . the validity *or amount* of a disputed claim") (emphasis added). Distributors reserve the right to object at trial if Plaintiffs seek to introduce the DEA Settlements to establish the amount of their claims or for any other purpose.

establish relevance, Plaintiffs must show that evidence of the settlements make any "fact . . . of consequence" in these cases "more or less probable than it would be without the evidence." Fed. R. Evid. 401 (test for relevant evidence); *see also* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). To begin with, three of the six settlements with the DEA expressly disclaim any admission or concession of liability. Dkt. No. 1964-3 (Cardinal Health 2008 (Ex. 215)); Dkt. No. 1964-37 (McKesson 2008 (Ex. 249)); Dkt. No. 1964-86 (ABDC 2007 (Ex. 298)). Of the three agreements that do contain narrow admissions, *none* implicates distribution of opioids into Summit and Cuyahoga counties.

- Cardinal's 2012 MoA arose out of a DEA investigation of seven specific facilities in California, Colorado, Florida, Georgia, New Jersey, Texas, and Washington, Ex. 215 at 1-2—*none* of which distributes to Ohio pharmacies. The MoA mentions Cardinal Health's Ohio facilities only as part of a list of facilities ***not*** investigated. Ex. 215 at 13.

- McKesson's 2017 settlement contains allegations relating to twelve distribution centers, none of which is the New Castle, PA facility that services Summit and Cuyahoga counties. The settlement also does not identify any particular pharmacies or shipments in Ohio, nor are there any admissions concerning McKesson's operations in Ohio.

- Neither ABDC's April 19, 2007 Initial Suspension Order nor the June 22, 2007 Settlement Agreement contains allegations concerning distribution of opioid medications to Cuyahoga or Summit pharmacies specifically, or to Ohio pharmacies generally.

Similarly, Cardinal Health, ABDC, and McKesson's settlements with West Virginia neither admit fault nor concern shipments of prescription opioids to any place other than West Virginia.

And, notwithstanding the narrow admissions contained in three of the settlements, the agreements are not relevant, because any reference to them would necessarily depend on a "if it happened there, it must be happening here" premise—which is, as Plaintiffs have acknowledged, invalid. Dkt. No. 2212 at 9, 30 (citing *In re Chocolate Confectionary Antitrust Litig.*, 801 F.3d 383, 402 (3d Cir. 2015) (quoting Areeda & Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF

ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 1421a, at 160); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 51-52 (2d Cir. 2007)).

The narrow admissions are also irrelevant because they do not establish any element of Plaintiffs' claims. For the RICO claims, Plaintiffs must establish (inter alia) a *knowing or intentional* violation of the CSA statute—and none of the settlements admits to any such knowing or intentional wrongdoing.[2] Similarly, for the nuisance claim, violation of the CSA is irrelevant because the CSA is not a safety statute.[3]

The Settlements Are Inadmissible Under Rule 403. Even if the settlements had some relevance (which they do not), they still would be inadmissible under Rule 403, which requires the exclusion of evidence "if its probative value is substantially outweighed" by the "danger" of "unfair prejudice" or "confusing the issues." Fed. R. Evid. 403. Admission of the settlements would unfairly prejudice the Distributors and cause jury confusion. As the Sixth Circuit has explained, "the potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound" and would, if allowed, undermine the "'strong public interest' in encouraging settlement negotiations." *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 800, 805 (6th Cir. 2007) (quoting *Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 332 F.3d 976, 980 (6th Cir. 2003)).[4]

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[2] 21 U.S.C. §§ 841, 843 ("[I]t shall be unlawful for any person knowingly or intentionally . . . ."); *see* 18 U.S.C. § 1961(1)(D) (predicate acts limited to "felonious" conduct).

[3] *Taylor v. City of Cincinnati*, 143 Ohio St. 426, 433 (1944) (a statute is a "safety statute" only if it sets forth a "specific legal requirement for the protection" of the plaintiff and those similarly situated); *see* Opinion & Order (Dkt. No. 1680) at 24 (CSA "was not intended to protect [governments] from spending more on addiction-related public services").

[4] Underscoring both the importance of the bar on the admission of settlement agreements, the Sixth Circuit has explained that the public interest in settlement negotiations would be undermined if settling parties enjoyed only thin "veneer of protection" offered by curative instructions. *Id.* at 805. The Court, accordingly, has "reject[ed] the proposition that any amount of evidence supporting liability, . . . coupled with a limiting instruction read at any time during the trial is sufficient to cure the wrongful admission" of settlement evidence. *Id.*; *see also* 2 Jack B. Weinstein & Margaret A. Berger, *Weinsten's Federal Evidence* § 408.11[1][a] (2d ed. 2017) ("The failure to

2. [D-2] The Court Should Preclude Non-Party Corporate Representatives From Testifying To Matters Outside Their Personal Knowledge

The Court should preclude Plaintiffs from offering testimony, whether live or by deposition, of non-party corporate representatives (Rule 30(b)(6) witnesses) on matters outside the witnesses' personal knowledge. This bar should extend to testimony based on hearsay conversations with other employees, review of documents, and other sources consulted by the witness to prepare to testify as a corporate representative. Information derived from such sources is properly offered in discovery under Rule 30(b)(6), but it is not admissible at trial.

Several examples arose in the Rule 30(b)(6) deposition of DEA employee Thomas Prevoznik. Mr. Prevoznik joined the DEA 28 years ago. See Prevoznik Tr. (Dkt. No. 1983-9) at 26:13-14, 42:15-17; 83:2-5. But he testified regarding events and documents that predated that period, such as a report compiled in 1987. *See* Prevoznik Tr. (Dkt. No. 1983-11) at 803:16-806:4. He also testified more generally about matters of which he had no personal knowledge. For example, Mr. Prevoznik identified a document as a presentation made by the DEA after admitting, "I've never seen this before." *Id.* at 981:15-986:5.

At trial, a lay witness's testimony is limited to matters within his or her personal knowledge. Fed. R. Evid. 602. The witness's own testimony may be used to provide evidence proving such personal knowledge exists. *Id.* But that testimony still is subject to the hearsay restrictions in Rules 801 and 805. Fed. R. Evid. 602 advisory committee's note.

This rule does not change for a non-party 30(b)(6) witness.[5] The 30(b)(6) designation "does not create a hearsay exception allowing him [at trial] to simply repeat statements made by corporate officers and employees, if those statements are offered for their truth." *Cooley v.*

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exclude evidence of an offer or a completed agreement . . . is sufficiently prejudicial to warrant a mistrial, even if there has been an admonition.").

[5] Deposition testimony given by a ***party*** under Rule 30(b)(6) may under some circumstances be admissible against that party as a party admission. This motion focuses on ***non-party*** 30(b)(6) testimony.

Lincoln Elec. Co., 693 F.Supp.2d 767, 791 (N.D. Ohio 2010). The prohibition on using 30(b)(6) witnesses as conduits for hearsay is especially important when the proponent does not offer any "independent evidentiary basis that might otherwise prove the truth of the hearsay." *Id.* at 792.

Although Rule 30(b)(6) gives broad latitude for the representative to speak about corporate knowledge at a deposition, that right is significantly narrowed by the hearsay rule that applies *at trial*. "[A] corporate representative may not testify to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.'" *Union Pump Co. v. Centrifugal Technology Inc.*, 404 F. App'x 899, 907-08 (5th Cir. 2010) (quoting *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 435 (5th Cir. 2006))).

Therefore, while plaintiffs may offer otherwise admissible testimony from Mr. Prevoznik or other third-party 30(b)(6) designees that reflects their own personal knowledge, testimony that is not based on personal knowledge is hearsay and lacks foundation and is therefore inadmissible.

3. [D-3] The Court Should Exclude Any Evidence Of Criminal Indictments And Investigations Without Corresponding Proof Of A Final Judgment Of Conviction

Plaintiffs' proposed exhibit list includes indictments (as well as press releases announcing indictments) that allege misconduct in the distribution, prescription, and dispensing of opioid medications. The fact that someone has been indicted amounts to "no more than an accusation, *i.e.*, alleging that the defendant committed the crime." 3 Fishman & McKenna, *Jones on Evidence* § 17:34 (7th ed.); *see also, e.g.*, *Ruffalo's Truck. Serv. v. Nat'l Ben-Franklin Ins. Co.*, 243 F.2d 949, 953 (2d Cir. 1957) ("The indictment, since it was only hearsay, was clearly inadmissible for any purpose."); *United States v. Olivieri*, 740 F. Supp. 2d 414, 419 (S.D.N.Y.

2010) ("Charging Instruments are hearsay."). The Court should therefore exclude these exhibits, related testimony and press releases, and any other evidence concerning criminal indictments.[6]

To be sure, an indictment may be introduced "under Rule 803(22), which excepts judgments of previous *convictions* from the general ban against hearsay." *Mike's Train House, Inc. v. Lionel, LLC,* 472 F.3d 398, 412 (6th Cir. 2006) (emphasis added). But to satisfy this exception, plaintiffs would need to present a corresponding *judgment of conviction* that meets the strictures of Rule 803(22), including that the judgment be final and entered after a trial or guilty plea. *See id.* The point remains that a mere indictment will not suffice. *Cf. Munsey v. Tactical Armor Prods., Inc.*, No. 07-CV-445, 2008 WL 4500130, at *1 (E.D. Tenn. Sept. 30, 2008) ("The Court agrees with defendants that the Superseding Indictment is hearsay that does not fall within any hearsay exception."). Indeed, the fact that an indictment might satisfy a hearsay exception *when accompanied by a corresponding conviction* only underscores the default rule that an indictment standing alone is inadmissible. *See Gritton*, 2007 WL 3407459, at *10 ("Absent a conviction, it follows that these indictments do not come within the scope of Rule 803(22) and remain inadmissible hearsay."). And even such a conviction is admissible only if admitted to prove a fact "essential to the judgment." Fed. R. Evid. 803(22)(C).

Even if plaintiffs purport to offer an indictment for reasons other than the truth of its underlying allegations, the indictment would be inadmissible under Rule 402. The mere fact that the government has indicted someone has no relevance independent of the truth of the underlying allegations, given that "an indictment is not *any* evidence of guilt." *United States v. Chance*,

[6] The general bar against admitting criminal indictments carries special force because "indictments may be issued where the entire basis of evidence against the criminal defendant is hearsay." *Gritton v. Disponett*, No. 3:05-cv-75-JMH, 2007 WL 3407459, at *10 n.12 (E.D. Ky. Nov. 14, 2007). In other words, not only are indictments themselves hearsay, they may rest on nothing but hearsay—further compounding their unreliability. Given those shaky foundations, "there are no circumstantial guarantees of trustworthiness which would render [criminal indictments] admissible under the residual exception." *Levinson v. Westport Nat. Bank*, Nos. 09cv269(VLB), 09–cv–1955(VLB), 10cv261(VLB), 2013 WL 2181042, at *1 (D. Conn. May 20, 2013).

306 F.3d 356, 385 (6th Cir. 2002) (emphasis added); *see also In re Knerr*, 361 B.R. 858, 862 (Bankr. N.D. Ohio 2007) (striking state court indictment "[b]ecause an indictment is not evidence of any kind against a defendant and does not create any presumption or permit any inference of guilt" (internal quotation marks and citation omitted)). The only relevance of an indictment depends on the truth of its allegations. And because "indictments do not prove that any of the conduct described therein actually occurred," they should be excluded as irrelevant. *Chen v. Mayflower Transit, Inc.*, 315 F. Supp. 2d 886, 923 (N.D. Ill. 2004).[7] Despite the lack of any probative value, introduction of indictments would also create a substantial risk of unfair prejudice, as an "indictment's official nature" lends an undeserving imprimatur of credibility to its allegations that risks misleading and confusing the jury. *Baxter Health Care Corp. v. Spectramed Inc.*, No. SA CV 89-131, 1992 WL 340763, at *3 (C.D. Cal. Aug. 27, 1992).

The grounds for excluding evidence of ongoing criminal investigations are equally compelling. Like an indictment, the mere existence of a criminal investigation is not evidence admissible against a defendant. Even if an ongoing criminal investigation could be deemed to have some minimal probative value, that probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury—and thus should be excluded under Rule 403. *See Spencer v. McDonald*, 705 F. App'x 386, 390 (6th Cir. 2017) (affirming decision to exclude evidence of a criminal investigation because "[e]ven if the investigation were relevant" to the issues in the civil case, the district court did not abuse its discretion in excluding it under Rule 403); *Park W. Galleries, Inc. v. Glob. Fine Art Registry, LLC*, Nos. 08–cv–12247, 2:08–cv–12274, 2010 WL 848689, at *1 (E.D. Mich. Mar. 8, 2010) (excluding evidence of an FBI investigation under Rule 403 because "'[t]he probative value of

[7] Many of the indictments on Plaintiffs' list are also irrelevant because they relate only to allegations occurring outside of the Plaintiff counties.

an ongoing criminal investigation is substantially outweighed by the danger of unfair prejudice, confusion of the issues and misleading the jury'") (quoting *Fidelity Nat'l Title Ins. Co. of N.Y. v. Intercounty Nat'l Title Ins. Co.,* Nos. 00 C 5658, 00 C 7086, 2003 WL 2005233, at *10 (N.D. Ill. Apr. 30, 2003)). Rule 403 applies not only to documents and testimony on direct examination, but also to questions on cross-examination. *See United States v. Newsom*, 452 F.3d 593, 602-04 (6th Cir. 2006) (agreeing that "the district court erred in allowing the government to cross-examine his other witnesses . . . because the resulting evidence violated Rule 403"); *Spencer*, 705 F. App'x at 392 (affirming the disallowance under Rule 403 of an impeachment question on cross-examination regarding a criminal investigation).

For these reasons, the Court should exclude any evidence of criminal investigations or indictments without corresponding proof of a final judgment of a conviction.

4. [D-4] The Court Should Prohibit Plaintiffs From Stating Expressly Or Suggesting That The Jury May Infer That An Older Document Never Existed Just Because It Cannot Be Found

At his deposition, Plaintiffs' DEA expert James Rafalski offered his opinion that customer due diligence records and suspicious order reports "should be kept forever."[8] Then, in forming his opinions about alleged violations of the Controlled Substances Act, he assumed that if a distributor is unable to locate a due diligence file, this means the due diligence was not performed, even if the file would have been created in 1996, more than twenty years ago.[9] This assumption is the sole basis for Rafalski's conclusion that there was a "complete failure" by

[8] Rafalski Tr. (Dkt. No. 1983-15) at 125:5–126:3;

[9] *Id*. at 289:10-17.

Defendants to perform due diligence on customer orders[10] and is the basis on which Craig McCann, Plaintiffs' data expert, flagged all but a tiny percentage of orders as suspicious.[11]

The fact that suspicious order reports and due diligence files from five, ten, or twenty years ago cannot be located today does *not* mean they never existed. The Court should preclude Plaintiffs and their experts from drawing or suggesting this inference for two reasons: (1) it is contradicted by 30(b)(6) testimony from DEA and inconsistent with the CSA's record retention regulations, which impose no requirement to retain these records for any period of time, let alone "forever"; and (2) it does not satisfy the adverse inference test, as applied in the Sixth Circuit.

Inconsistent with DEA Testimony and the CSA. DEA's 30(b)(6) representative, Thomas Prevoznik, testified that there is no requirement to retain suspicious order reports that are submitted to DEA, and "there's no requirement that a due diligence file even be maintained."[12] That testimony is consistent with the record retention requirements outlined in Part 1304 of the CSA regulations, which governs records and reports. Those regulations impose several, explicitly defined recordkeeping requirements for certain categories of documents—*e.g.*, invoices, packing slips, inventories and records of controlled substances, paper and electronic prescriptions, and distribution records, *see* 21 C.F.R. §§ 1304.04, 1304.06, 1304.22—but impose *no* requirement that registrants retain suspicious order reports and due diligence documents at all, let alone "forever." For the specified records that must be retained, the regulations state that "every inventory and other records required to be kept under this part must be kept by the registrant and be available, for a period of *at least 2 years* from the date of such inventory or

[10] *Id*. at 188:2-10 ("It's not an assumption. It's based on my review of records and depositions and documents that I couldn't find a time period where I believed there was sufficient due diligence . . . there was actually a complete failure.").

[11] Expert Report of Craig McCann (Dkt. No. 1965-65) at 56-57.

[12] Prevoznik Tr. (Dkt. No. 1983-11) at 1219:1-4; 1220:20–1221:1.

records for inspection and copying by authorized employees of the Administration." 21 C.F.R. § 1304.04(a) (emphasis added); *see* Rafalski Tr. (Dkt. No. 1983-15) at 124:18-24 ("Any of the records that are in the records section of the CFR have a *two-year retention*") (emphasis added). Other than the requirements in Part 1304, the CSA imposes no other document retention requirements, including for suspicious order reports and due diligence documentation. Neither the CSA nor its regulations even mention due diligence documentation, let alone impose a record retention requirement. *See* Rafalski Tr. (Dkt. No. 1983-15) at 128:14-18 ("The CFR doesn't speak specifically to a due diligence record . . . .").

The inference that if a record presently does not exist, it never did, is a significant driver of Rafalski's assessment of Defendants' alleged failures, but he offers no basis for it other than a vague allusion to his experience, training, and knowledge.[13] He acknowledges that suspicious order reports and due diligence documentation are not subject to the two-year retention requirement in Part 1304,[14] but nevertheless maintains that if a registrant does not keep these documents indefinitely, it violates the requirement to "maintain effective controls against diversion."[15] Because that conclusion is contrary to the official testimony from DEA's designee, and has no basis in the CSA's record-retention requirements, the Court should preclude Plaintiffs from relying on this inference at trial.

Unsupportable Inference According to Sixth Circuit Test. The Sixth Circuit has established a three-prong test that must be met before the Court may order an adverse inference instruction based on the destruction of evidence. *Stocker v. United States*, 705 F.3d 225, 235 (6th Cir. 2013). Plaintiffs cannot meet this test. *First*, the moving party must establish "that the

[13] Rafalski Tr. (Dkt. No. 1983-15) at 172:5-12.

[14] *Id*. at 125:5-13;

[15] *Id.* at 128:7-18;

party having control over the evidence had an *obligation to preserve it* at the time it was destroyed." *Id*. (emphasis added) (internal quotation marks omitted). Because Defendants did not have an obligation to preserve suspicious order reports and due diligence records, including documents dating as far back as 1996, there is no basis to infer that their failure to retain the documents is evidence that they never existed. *Second*, the moving party must show "that the records were destroyed with a culpable state of mind." *Id.* (internal quotation marks omitted). Even if the Court were to credit Rafalski's testimony that Defendants had an obligation to maintain due diligence documentation "forever," Plaintiffs have no evidence that Defendants destroyed the records with a culpable state of mind.

5. [D-5] The Court Should Prohibit Plaintiffs From Presenting Evidence Or Making Arguments Suggesting Distributors Committed A "Fraud On The DEA"

The Court should bar Plaintiffs from presenting testimony, offering other evidence, and making arguments to the jury suggesting that Distributor Defendants engaged in a "fraud on the DEA."

Plaintiffs have disclaimed pursuing claims based on a "fraud on the DEA" theory; and, regarding Plaintiffs' deceptive marketing theories, the Court has held that they do not concern fraud on the DEA. Opinion and Order re: Preemption, In re Nat'l Prescription Opiate Litig., MDL No. 2804 (Sept. 3, 2019) (Dkt. No. 2565) at 22 ("Plaintiffs have not alleged a claim for fraud on a federal agency, . . . Plaintiffs' claims are not impliedly preempted under *Buckman* [*Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001)]."); *id.* at 9 ("Plaintiffs' marketing-based claims are not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman*.").

But Plaintiffs' due diligence-based claims—*i.e.*, those claims based on Distributors' alleged failure to report suspicious orders—do inherently assert a fraud on the DEA. Plaintiffs and their experts have said repeatedly that Distributors, by failing to report suspicious orders to

DEA, misled the agency, and, but for that deception, DEA and state and local authorities would have acted to police the excess prescribing of opioids. This is a classic fraud-on-the-agency argument, and impermissible under *Buckman*. In *Buckman*, the Supreme Court held that where federal agencies are endowed with the authority to detect, police, and prosecute suspected frauds against them—as DEA and FDA are—federal law impliedly preempts state law claims that rely on an alleged lack of candor or fraud in submitting required information to the agency. 531 U.S. at 347-53. "Lower courts have applied *Buckman*'s reasoning to other federal statutory schemes." *Kobar ex rel. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171 (D. Ariz. 2005) (collecting authorities). "Indeed, in every case where a court has analyzed whether a federal regulatory scheme preempts state law claims that require a plaintiff to prove as an essential element fraud on the federal agency responsible for administering the federal scheme, the court has found preemption of the state law claim." *Id.* at 1174.

Plaintiffs should be precluded from offering any testimony, evidence, or argument that Distributor Defendants have misled the DEA by failing to report suspicious orders, or otherwise failing to submit required information. This testimony, evidence, and argument would be irrelevant, prejudicial, and would risk confusing the jury. *See* Fed. R. Evid. 402, 403

6. [D-6] The Court Should Prohibit Counsel And Witnesses From Making References Broadly And Generally To "Defendants" When The Statement, Argument, Or Testimony Relates Only To Certain Specific Defendants Or Groups Of Defendants

Plaintiffs' claims in these cases rest on allegations that in many instances target only individual defendants or small subsets of the defendants. For example, Plaintiffs allege, repeatedly, that certain defendants deceptively marketed prescription opioids to doctors. Those allegations only implicate—indeed, *can* only implicate—the manufacturers. They do not involve the distributor defendants. Yet on this subject, among others, Plaintiffs and their witnesses are

routinely careless in speaking of alleged conduct by "defendants" without specifying about whom they are actually talking.

This carelessness can cause confusion, as was demonstrated in the expert report and deposition of Dr. Anna Lembke, one of Plaintiffs' experts. Dr. Lembke repeatedly referred to allegedly "misleading messaging by the *defendants*," *see* Lembke Tr. (Dkt. No. 1979-17) at 46:4, "false promotional statements on the part of *defendants*," (*id.* at 91:12-13), "misrepresentation of the evidence by the *defendants*," (*id.* at 223:9-10), and many similar statements. (Emphasis added). Later in the deposition when, pressed by attorney questioning, Dr. Lembke clarified that *none* of her references to "defendants" and the "industry" referred to the distributor or pharmacy defendants. (*Id.* at 267:25-268:11, 274:8-275:18.) In fact, Dr. Lembke had no opinions of any kind to offer about those defendants.

Such careless "lumping" violates Rule 403. The Court is entitled to exclude evidence if its probative value is substantially outweighed by danger of (1) unfair prejudice, (2) confusing the issues, (3) misleading the jury, (4) undue delay, (5) wasting time, or (6) needlessly presenting cumulative evidence. Fed. R. Evid. 403. There is no dispute that referring broadly to "defendants" rather than the proper subset has no probative value. On the converse, doing so poses all of the dangers Rule 403 was designed to prevent:

Unfair Prejudice: Attributing bad facts about "misrepresentation" and "misleading messaging" to parties that took no part in such actions, as Dr. Lembke did, risks unfairly prejudicing the jury against those parties.

Confusing the Issues or Misleading the Jury: "Lumping" can prevent a jury from properly allocating liability to individual defendants when they are entirely distinct entities. *Contra Rui He v. Rom*, No. 15–cv–1869, 2017 WL 1054814, at *5 (N.D. Ohio, Mar. 21, 2017)

(holding that "lumping" on jury form was not problematic because the jury "had no reason to allocate fault between the various Defendant Companies because they were a single, veil-less entity"). Where jurors must make distinctions between defendants, and evidence is presented in an undifferentiated manner, jurors are likely to be confused about *which* defendants are being discussed at any given time, and will be unable to attribute testimony or argument to the specific defendants to which it actually relates. *See Reo v. Caribbean Cruise Line, Inc.*, No. 14 CV 1374, 2016 WL 1109042, at *3 (N.D. Ohio, Mar. 18, 2016) (noting that a complaint using "Defendants" to refer to allegations against only some parties was "sloppy and mildly confusing").

Undue Delay, Wasting Time, or Cumulative Evidence: One of the many reasons "lumping" of parties is problematic is that it does not give individual defendants adequate notice of the charges against them. It is for this reason that "lumping" of parties in a complaint is a basis for dismissal under Rule 12(b)(6). *See Marcilis v. Township of Redford*, 693 F.3d 589, 596 (6th Cir. 2012) (affirming district court dismissal of complaint against two defendants whose conduct was not alleged with particularity); *see also Seri v. Crosscountry Mortgage, Inc.*, No. 16–cv–01214, 2016 WL 5405257, at *4 (N.D. Ohio, Sept. 28, 2016) (dismissing complaint in part because plaintiffs "lumped" defendants together and thereby failed to "give the defendant fair notice of what the claim is and the grounds upon which it rests.") (internal quotation marks omitted). "Lumping" at trial is even worse, because it forces individual defendants to use valuable court time to cross-examine witnesses to clarify how they are using "defendants," object to counsel's use of the generic term "defendants," or take the time to parse and counter what they said. If each individual defendant is forced repeatedly to stave off such misunderstandings, such

efforts will inevitably waste time, at best, and, most likely, will lead to ongoing and continuous confusion.

7. [D-7] The Court Should Preclude Plaintiffs From Offering Evidence Of, And Arguments About RICO Predicates That Plaintiffs Did Not Identify In Their Discovery Responses.

In an interrogatory, Distributors asked Plaintiffs to identify the "predicate acts" on which they rely in support of their RICO and OCPA claims. In response, Plaintiffs identified only (i) mail and wire fraud and (ii) purported false or fraudulent statements to DEA. *See* Plaintiffs' Supp. Responses to Distributor Defendants' Interrogatories 24, 25, 26, and 27, at 4. Accordingly, Plaintiffs should be barred from presenting evidence or argument that Distributors committed any predicate acts other than those timely identified in their Interrogatory Responses. *See Bridgeport Music, Inc. v. WM Music Corp.*, 508 F.3d 394, 400 (6th Cir. 2007) (holding that a plaintiff may not "expand its claims to assert new theories" at the summary judgment stage or beyond); *Vystrcil v. Mercy Health*, No. 17CV781, 2019 WL 2076035, at *4 (N.D. Ohio May 10, 2019) (holding that "Plaintiffs may not expand the scope of their claims" to allege violation of a different underlying statute on summary judgment (citing *Tucker v. Union of Needletrades, Indus., & Textile Emps.*, 407 F.3d 784 (6th Cir. 2005))); *see also Feinstein v. Resolution Tr. Corp.*, 942 F.2d 34, 42 (1st Cir. 1991) ("It is not enough for a plaintiff to file a RICO claim, chant the statutory mantra, and leave the identification of predicate acts to the time of trial.").

8. [D-8] The Court Should Issue An Order Excluding Any Evidence Of, Or Reference To, Distributor-Run Programs That Allowed Manufacturers To Communicate Product Information To Pharmacies Or Other Parties

The Court should issue an order excluding any evidence of, or reference to, Distributor-run programs that allowed manufacturers to communicate product information to pharmacies or other parties. Plaintiffs have expressly admitted that their claims do not in any way relate to

purported "marketing" by Distributors. *See* Dkt. No. 2182, at 82 (admitting that Distributors "did not join the Opioid Marketing Enterprise"). Given this unequivocal admission, Plaintiffs inclusion of many documents relating to these programs as trial exhibits is inexplicable. *See, e.g.*, P-8161; P-8165. All such documents, and any other reference to these programs, should be excluded as irrelevant, *see* Fed. R. Evid. 402, and because their admission would create a substantial and unavoidable risk of jury confusion and unfair prejudice, *see* Fed. R. Evid. 403.

Plaintiffs' RICO and OCPA claims against Distributors relate to an alleged "Supply Chain Enterprise" focused on alleged "eva[sion of] state and federal diversion controls" in the development and maintenance of their suspicious order monitoring programs. *See, e.g.*, Dkt. No. 2182 at 4. These claims in no way relate to the programs, offered by certain distributors, through which manufacturers provided basic product information to pharmacies and others.[16] To the contrary, Plaintiffs have alleged a ***separate*** "Marketing Enterprise" against manufacturers only. *Id.* at 1. Moreover, Plaintiffs have expressly disavowed any suggestion that these distributor-operated programs are relevant to their civil conspiracy claim and have admitted that the conspiracy claim is "*not based on opioid marketing*." *Id.* at 114 (emphasis added).[17] The program materials therefore are irrelevant. *See Sanco, Inc. v. Ford Motor Co.*, 771 F.2d 1081, 1087 (7th Cir. 1985) (affirming exclusion of evidence that only a supported a theory plaintiffs did not proceed under at trial); *Mendelsohn v. Sprint/United Mgmt. Co.*, 587 F. Supp. 2d 1201, 1217 (D. Kan. 2008), *aff'd*, 402 F. App'x 337 (10th Cir. 2010) (admissibility of evidence requires a showing that the evidence relates "to the plaintiff's circumstances and theory of the case").

[16] Plaintiffs own expert, Dr. Perri, acknowledges that the Distributor programs in question only provide price and availability information "to pharmacies and other buyers"—not prescribers—and "do not generate patient level demand." Perri Tr. (Dkt. No. 1983-4) at 218:17–219:6, 224:19-2.

[17] Even with respect to any marketing claims against manufacturers participating in the trial, any distributor programs involving those manufacturers are still irrelevant. Plaintiffs' claims against manufacturers relate to efforts to "drastically expand the market" for opioid medication by deceiving prescribers. *See, e.g.*, Summit TAC ¶¶ 1, 775; Cuyahoga TAC ¶¶ 1, 821. Distributors' programs did not do that. *See* n.16.

In light of Plaintiffs' admissions regarding relevance, the only possible purpose for Plaintiffs' inclusion of these materials on their exhibit list is to confuse the jury by blurring the distinction between Distributors and Manufacturers in an effort to have the jury assign blame for the alleged "Marketing Enterprise" to Distributors. *See Sidari v. Orleans Cnty.*, 174 F.R.D. 275, 282 (W.D.N.Y. 1996) ("A lumping together of such claims, which amounts to guilt by association, would unfairly prejudice the defendants."); *Deskovic v. City of Peekskill*, 673 F. Supp. 2d 154, 171 (S.D.N.Y. 2009) (recognizing the possibility of "spill-over" prejudice between claims brought against different defendants). The risk of confusion is particularly strong here where Plaintiffs acknowledge that the materials in question—unlike Manufacturers' very different marketing activities—had no impact on the "increased demand" for opioids that form the heart of their case against Manufacturers. *See supra* n.16.[18] In this incredibly time-compressed trial setting, where each Defendant has only limited time to address and respond to Plaintiffs' allegations, the possibility of jury confusion on these points is only heightened.

The Court should exclude trial exhibits relating to, or referencing, Distributor-run programs that allowed manufacturers to communicate their product information to pharmacies and other parties.

[18] While all such evidence and argument should be excluded, program materials involving the products of manufacturers that do not appear at trial are particularly objectionable. For those products, there is a substantial risk that the jury will be misled into holding Distributors to account for product information drafted, controlled, and warranted to be FDA-compliant by the manufacturers no longer at trial.

III. CONCLUSION

For the reasons stated above, Distributor Defendants request that the Court grant Defendants' Omnibus Motions in Limine.

Dated: September 25, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Robert A. Nicholas, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Robert A. Nicholas
Robert A. Nicholas

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' OMNIBUS RESPONSE TO DEFENDANTS' MOTIONS *IN LIMINE* (DKTS. #2645, #2648, #2653, #2661, #2663, #2666, #2668) AND MEMORANDUM IN SUPPORT

October 7, 2019

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INTRODUCTION

Plaintiffs submit this omnibus response to the following motions *in limine* filed by Defendants: Omnibus Memorandum of Law in Support of All Track One Bellwether Trial Defendants' Motion in Limine (Dkt. #2661); Omnibus Memorandum of Law in Support of Distributor Defendants' Motions in Limine (Dkt. #2666); Henry Schein Defendants' Motions in Limine (Dkt. #2645); Walgreens' Motions *in Limine* (Dkt. #2648); Cardinal Health Inc.'s Motions *in Limine* (Dkt. #2653); McKesson Corporation's Motion in Limine to Exclude Certain Evidence and Argument (Dkt. #2663); and Teva Defendants' and Actavis Generic Defendants' Omnibus Motion in Limine (Dkt. #2668).[1] This omnibus response is designed to reduce the documents on this Court's docket and promote brevity.

The MILs proposed by Defendants should be denied.[2] As a preliminary matter, Plaintiffs are unclear if Defendants have not read this Court's summary judgment rulings, or have simply chosen to ignore them, but many of their MILs seek to re-litigate issues on which they have already lost. This is not an appropriate use of a motion *in limine*. Additionally, Defendants' legal and factual arguments in support of exclusion are without merit. Many of the cases Defendants cite do not even address motions *in limine* or evidentiary issues, and those that do are easily distinguishable. Defendants do not come close to satisfying their burden to demonstrate that the evidence sought to be excluded is clearly inadmissible on all grounds. And most of their MILs are overly broad and vague. Accordingly, Defendants' MILs should be denied and any evidentiary ruling should be deferred until trial so that questions of relevancy and potential prejudice may be resolved in proper context.

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1 All Exhibits referenced herein as are attached to the Appendix in Support of Plaintiffs' Omnibus Response to Defendants' Motions *in Limine*, filed contemporaneously herewith.

2 There are two exceptions. Plaintiffs will agree to the Teva/Actavis Defendants' MIL No. TAD-10. *Infra* at § G.10. Additionally, the parties have agreed to stipulate to a modified version of Defendants' Omnibus MIL No. 13 (*infra* at § A.13) and informed Special Master Cohen of this agreement by e-mail on September 30, 2019.

LEGAL STANDARD

The Sixth Circuit states: "Orders in limine which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise." *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975).[3] Thus, the Court "has the power to exclude evidence in limine only when evidence is *clearly inadmissible* on all potential grounds." *Indiana Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004) (emphasis added).[4] Relevant evidence is generally admissible. FED. R. EVID. 402. "Evidence is relevant if: (a) it has *any* tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." FED. R. EVID. 401 (emphasis added). This is an " 'extremely liberal' " standard. *Dortch v. Fowler*, 588 F.3d 396, 400 (6th Cir. 2009)(citation omitted). Courts may exclude relevant evidence, however, "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." FED. R. EVID. 403. To be excluded on prejudice grounds, the evidence cannot just be prejudicial; it must be *unfairly* prejudicial. *Robinson v. Runyon*, 149 F.3d 507, 514 (6th Cir. 1998). " 'Unfair prejudice does not mean the damage to a defendant's case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest a decision on an improper basis.' " *Id.* at 515 (citation omitted). Even when the evidence is "shaky," " 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking' such evidence, not exclusion." *Id.* (citation omitted).

The moving party bears the burden of demonstrating that the evidence sought to be excluded is clearly inadmissible. *See Jordan*, 2010 WL 4281807, at *1 (" 'A court will generally not grant a motion in limine unless the moving party meets its burden of showing that the evidence in

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3 *See also Morningstar v. Circleville Fire & EMS Dept.*, 2:15-CV-3077, 2018 WL 3721077, at *1 (S.D. Ohio Aug. 6, 2018) (same).

4 *See also Jordan v. John Soliday Fin. Group, LLC*, 1:09CV0707, 2010 WL 4281807, at *1 (N.D. Ohio Oct. 20, 2010) (same); *St.-Gobain Autover USA, Inc. v. Xinyi Glass N.A., Inc.*, 1:06CV2781, 2009 WL 10689369, at *1 (N.D. Ohio Oct. 23, 2009).

question is clearly inadmissible.' ") (citation omitted). "Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Indiana Ins.*, 326 F. Supp. 2d at 846.[5] The Court has broad discretion in determining whether to grant or deny a motion *in limine*. *St.-Gobain*, 2009 WL 10689369, at *1 ("Ultimately, the determination whether to grant or deny a motion in limine is within the sound discretion of the trial court.").

Moreover, motions *in limine* are meant to address evidentiary issues; they should not be used to resolve non-evidentiary factual or legal disputes. As the Sixth Circuit explained:

> [A] mechanism already exists in civil actions to resolve non-evidentiary matters prior to trial—the summary-judgment motion. Allowing a party to litigate matters that have been or should have been resolved at an earlier stage not only allows those dissatisfied with the court's initial ruling a chance to relitigate, but also deprives their opponents of the procedural protections that attach at summary judgment.

Louzon v. Ford Motor Co., 718 F.3d 556, 561 (6th Cir. 2013). Thus, when a motion *in limine* "is no more than a rephrased summary-judgment motion, the motion should not be considered. *Id.* at 563. *See also Morningstar*, 2018 WL 3721077, at *7 (same).

The fact that the Court denies a motion *in limine* "does not necessarily mean that all evidence contemplated by the motion will be admitted at trial." *Indiana Ins.*, 326 F. Supp. 2d at 846.[6] It simply means that "without the context of trial, the [C]ourt is unable to determine whether the evidence in question should be excluded." *Indiana Ins.*, 326 F. Supp. 2d at 846.[7] The movant may still raise objections to the introduction of the evidence during the trial.[8]

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5 *See also Jordan*, 2010 WL 4281807, at *1 ("If this burden is not met, evidentiary rulings should be deferred and resolved in the context of the trial."); *St.-Gobain*, 2009 WL 10689369, at *1 ("If the court is unable to determine whether or not certain evidence is clearly inadmissible, it should defer ruling until trial so that questions of foundation, relevancy, and potential prejudice can be evaluated in the proper context.").

6 *See also Securities and Exch. Commn. v. Jacobs*, 1:13 CV 1289, 2014 WL 12597832, at *2 (N.D. Ohio Feb. 25, 2014); *Jordan*, 2010 WL 4281807, at *1.

7 *See also Securities*, 2014 WL 12597832, at *2 ("Where a court denies a motion *in limine*, it is, in essence, a finding that the court cannot determine whether it can exclude the evidence without the context of trial."); *Jordan*, 2010 WL 4281807, at *1.

8 *Indiana Ins.*, 326 F. Supp. 2d at 846 ("The court will entertain objections on individual proffers as they arise at trial, even though the proffer falls within the scope of a denied motion in limine."); *Jordan*, 2010

ARGUMENT

A. PLAINTIFFS' RESPONSE TO OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF ALL TRACK ONE BELLWETHER TRIAL DEFENDANTS' MOTION IN LIMINE (DKT. #2661).

1. Defendants' Omnibus MIL No. 1: The Court should not permit Plaintiffs to present evidence or argument to the jury concerning "future damages."

Defendants seek to exclude evidence of Plaintiffs' future damages on the ground that Plaintiffs failed timely to disclose that they were seeking these damages. The record shows otherwise: Plaintiffs specifically identified future damages in their interrogatory responses as a category of damages they were seeking and specifically noted the overlap between their claims for future damages and their claim for abatement. When Plaintiffs learned that the two remedies would not be tried together, they promptly provided supplemental tables from their previously-disclosed experts, Prof. Jeffrey Liebman and Prof. Thomas McGuire, to separate the two forms of relief, and offered the experts who provided the supplemental tables for additional deposition time. Under these circumstances, Defendants cannot fairly claim surprise or prejudice to justify exclusion of this evidence.

i. Plaintiffs long ago disclosed that they are seeking future damages.

On November 30, 2018, Plaintiffs served their Second Supplemental Response and Objections to Distributor Defendants' Interrogatory No. 18. In those responses, Summit County and Cuyahoga County each stated: "Plaintiff seeks, *inter alia*, damages in the amounts as set forth below, which reflect both past damages from at least 2006 to present, *and future damages for at least 10 years*. Plaintiff's investigation of both its past and future costs, expenditures, damages, losses or harms caused by Defendants is ongoing. . . ." *See* **Ex. 1** [Summit Rog Resp.] at p. 6; **Ex. 2** [Cuyahoga Rog Resp]. at p. 7 (emphasis added). Each response further disclosed:

> To the extent Plaintiff is seeking future damages as set forth above, various components and subparts may either overlap, be a component part of, or be incidental to the equitable remedy sought as part of a comprehensive abatement plan

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WL 4281807, at *1 (same).

> should the Court enter such a plan, including the provision of funds necessary to implement the abatement plan.

Ex. 1 [Summit Rog Resp.] at p. 8; **Ex. 2** [Cuyahoga Rog Resp]. at p. 9. Finally, each response identified by name "the following persons with knowledge of such damages. . . ." *Id.* Thus, Defendants were informed 11 months before the start of the trial both that Plaintiffs were seeking future damages and that the components of future damages would overlap with the components of any comprehensive abatement plan. They were also provided with the names of fact witnesses concerning Plaintiffs' damages.

Plaintiffs also timely disclosed expert witnesses concerning damages. In March 2019, Plaintiffs disclosed their expert reports, including reports from Prof. Jeffrey Liebman and Prof. Thomas McGuire. Prof. Liebman's report set forth a detailed abatement plan to address the opioid crisis in Summit and Cuyahoga Counties over the period 2020-2034. Prof. Liebman quantified the cost of the abatement plan, offering the opinion that

> In Cuyahoga, the 15-year costs for the elements of the Abatement Plan evaluated to date range from $3.5 billion to $4.5 billion. In Summit, the 15-year costs range from $1.5 billion to $2.0 billion.

Dkt. #2000-11 (Liebman Expert Rep.) at p. 30. There was, of course, no doubt that all of this money would be expended in the future. In the meantime, Prof. Thomas McGuire quantified the past costs of the opioid epidemic, offering the opinion that "[i]n total for both Bellwether governments, damages from 2006 through 2018 range from to $194.4 - $223.4 million." Dkt. #2000-17 (McGuire Expert Report) at p. 7. Prof. McGuire noted, as well that, "[t]o the extent any Bellwether government seeks damages at trial beyond 2018 attributable to defendants' misconduct, the same methodology set forth herein would be extended to those future years, subject to the assumption that there would be no material changes in the scope and extent of harms." *Id.* at p. 7 n.12.

Although Defendants focus on the McGuire and Liebman supplemental tables, their motion sweeps more broadly and asks the Court to exclude *all* evidence of future damages. To the extent that Plaintiffs rely on previously disclosed material, including previously disclosed fact witnesses and

previously disclosed expert testimony, to prove their future damages, there can be no possible claim of surprise or prejudice and no basis to complain about a "trial by ambush." None of this evidence of future damages should be excluded.

ii. Defendants offer no argument to support the exclusion of future damages evidence other than the McGuire and Liebman Supplemental Tables.

Defendants' entire argument for the exclusion of all evidence pertaining to future damages is based on the purported untimeliness of the McGuire and Liebman supplemental tables. But Plaintiffs have other evidence of future damages, including testimony of fact witnesses and testimony of expert witnesses as disclosed in March 2019. Defendants offer no basis to exclude any of that evidence.

Under Ohio state law (applicable to Plaintiffs' conspiracy and OCPA claims) or federal law (applicable to Plaintiffs' RICO claims), "a plaintiff is entitled to an award of damages to compensate him for losses which he is reasonably certain to incur in the future." *Galayda v. Lake Hosp. Sys., Inc.*, 1994-Ohio-64, 71 Ohio St. 3d 421, 425; *see also Daniels v. Northcoast Anesthesia Providers, Inc.*, 2018-Ohio-3562, ¶ 57 (Ct. App. 2018); *Bankers Trust Co. v. Rhoades*, 859 F.2d 1096, 1103 (2d Cir. 1988) (future damages recoverable under RICO unless the fact of their accrual is speculative or their amount and nature unprovable). Significantly, however, expert testimony is not required to prove future damages. *See Daniels*, 2018-Ohio-3562, ¶ 56 (*citing Sahrbacker v. Lucerne Prods., Inc.*, 52 Ohio St.3d 179, 179 (1990)). The authorities cited by Defendants do not show otherwise, under Ohio law or federal law; they merely provide illustrations of the potential use of expert testimony to establish the certainty of future damages in particular cases. So long as a jury can find and quantify future damages with the requisite level of certainty, there is no specific requirement of expert testimony.

In this case, Plaintiffs have sufficient evidence, besides the supplemental tables, so that the existence of future damages cannot be found, as a matter of law, to be speculative, nor the amounts unprovable. The testimony of Plaintiffs' addiction experts and of fact witnesses regarding the opioid epidemic in Ohio will sufficiently establish that, in the absence of treatment, opioid abuse problems persist. In light of this testimony, it hardly requires speculation to conclude that the Counties will

continue to incur losses in the future arising from the opioid epidemic. (Indeed, the entire predicate of Plaintiffs' abatement claim is that the nuisance will continue to inflict harm until it is abated.) As for the amount of future damages, that information, too, may be provided by fact witnesses from the Counties with knowledge of how much it costs to provide the services needed address the opioid abuse problem in the Counties. This is especially true because Plaintiffs' claims for future damages are in the alternative, not in addition, to their claim for an abatement remedy.[9] For this reason, the premise of this claim is that there is no abatement plan in place, so the amount of future damages need not account for the kinds of improvements one would expect an abatement plan to produce. And even without their supplemental charts, the expert testimony of Profs. Liebman and McGuire provides sufficient information about the services required to address the opioid crisis, the ongoing need for such services, and the cost of providing them that a jury could with reasonable certainty award future damages based on this information.[10] The McGuire report provides sufficient information for the jury to determine the ongoing damages to be incurred in the future, and the Liebman report provides sufficient information for the jury to identify the overlap between Plaintiffs' future damages and their abatement plan. No more is required. *See Pfahler v. Nat'l Latex Prod. Co.*, 517 F.3d 816, 837 (6th Cir. 2007) ("Damages cannot be speculative, but this only means that the fact of damages, not their amount, cannot be uncertain."); *TJX Companies, Inc. v. Hall*, 2009-Ohio-3372, ¶ 32, 183 Ohio App. 3d 236, 245 ("Damages are not rendered uncertain because they cannot be calculated with absolute exactness. It is sufficient if a reasonable basis of computation is afforded, although the result be only approximate."). Indeed, "[a] defendant whose wrongful conduct has rendered difficult the ascertainment of the precise damages suffered by the plaintiff, is not entitled to complain that they cannot be measured with the same exactness and precision as

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9 To the extent they are awarded both, Plaintiffs have already recognized a set-off will be necessary to avoid double recovery. *See* Dkt. #2660 (Plaintiffs' Trial Brief) at p. 4.

10 The Court has already found that the testimony of Profs. Liebman and McGuire is reliable and admissible. *See* Dkt. #2577 (denying motion to exclude testimony of Prof. McGuire); Dkt. #2519 (denying motion to exclude expert testimony regarding abatement costs).

would otherwise be possible." *TJX Companies*, 2009-Ohio-3372, ¶ 33, 183 Ohio App. 3d at 245; *see also J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 566–67 (1981) ("[I]t does not come with very good grace for the wrongdoer to insist upon specific and certain proof of the injury which it has itself inflicted.") (citation and internal quotation marks omitted).

In *Daniels*, the Ohio Court of Appeals held that, although the plaintiff's future damages had to be reduced to present value, the plaintiff was not required to offer expert testimony on that issue. 2018-Ohio-3562, ¶ 57. If a jury can make its own present value computation without expert guidance, so, too, a jury can determine the Counties' future damages from the testimony of the County's employees, the evidence of the ongoing nature of addiction and opioid misuse, the evidence of the costs of addressing the crisis in the past, and the evidence of what it would take to abate the problem going forward. Defendants cannot show that no jury could find the fact of future damages to be reasonably certain or make a reasonable estimate of what those damages will be.

In any event, the issue on this motion is not the sufficiency of Plaintiffs' future damages evidence, but its admissibility. As discussed above, no arguments of prejudice or surprise apply to evidence of future damages as presented by Plaintiffs' fact witnesses or as presented in expert reports that were disclosed in March 2019. Not only were Defendants informed that Plaintiffs would be seeking future damages, they were provided the names of Plaintiffs' fact witnesses with respect to damages and they were provided with the original Liebman and McGuire reports, which included, as noted above, the methodology that would be used to calculate future damages. Plaintiffs may properly rely on this evidence to prove their future damages at trial.

iii. Plaintiffs properly supplemented the expert reports of Profs. Liebman and McGuire to separate future damages from abatement costs.

Although Plaintiffs believe their fact and original expert evidence is sufficient to establish their future damages, the Counties should also be permitted to present testimony based on the supplemental tables prepared by Profs. Liebman and McGuire. Because Plaintiffs expected to try their legal claims together with their equitable abatement claim, Plaintiffs did not separately quantify their future damages. Rather, Plaintiffs believed that the jury would hear all of the evidence

concerning past damages and abatement, and could then determine all elements of damages based on that evidence. On September 16, 2019, however, the Court suggested that it might bifurcate the trial and hear evidence pertaining to nuisance abatement in a separate proceeding from the trial in which Plaintiffs will present their damages evidence. On September 24, 2019, the Court ordered such bifurcation. *See* Dkt. #2629. Prior to September 16, Plaintiffs had no notice that the Court intended to hear evidence pertaining to legal remedies separately from evidence pertaining to equitable abatement and had not planned to separate the evidence pertaining to those remedies.

At the September 16 conference the Court explained its concerns about allowing Plaintiffs to present their nuisance abatement evidence in same proceeding with the rest of their evidence:

> It seems to me what I am proposing is that a jury decide whether or not any of the Defendants are liable for public nuisance. And that's all the jury will decide with respect to public nuisance. There is not going to be any evidence or testimony about what any relief or abatement would be in the event there is nuisance, how much it would cost, who would do what, whatever.
>
> We are not going to take the time in the trial for that because the jury isn't going to decide it, and my concern is, it may confuse them, and they may jumble things up and conflate that with past damages.

Ex. 3 [9/16/19 transcript]. Thus, the Court made clear that the jury could not use the abatement plan to compute future damages or to offset future damages from abatement, because, in order to prevent confusion and prejudice to the Defendants, the full abatement plan would not be presented to the jury.

This change in the trial plan required Plaintiffs to adapt the presentation of their evidence.[11] In order to present their legal damages in a separate proceeding from their equitable abatement plan,

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[11] Defendants' suggestion that Plaintiffs sought to introduce evidence of future damages only when they learned that the Court, rather than the jury, would be the fact-finder with respect to the amount of the abatement remedy, *see* Dkt. #2661 at pp. 2-3, is entirely unfounded and contradicted by the record. First, as discussed above, Plaintiffs had identified future damages as a component of their damages on their legal claims in November, 2018. Second, Plaintiffs had always assumed that the Court would be the fact-finder with respect to the cost of the abatement remedy. Indeed, in Plaintiffs' Position Statement Regarding a Jury Trial on the Public Nuisance Claim (Dkt. #2598) (a well as in the corrected version of that document, *see* Dkt. #2601), Plaintiffs took the position that "there is no right to a jury trial on a public nuisance claim for abatement." Dkt. #2601 at p. 1. Plaintiffs also stated that they "take no position and defer to the Court's decision as to whether to use an advisory jury regarding that claim." *Id.* Thus, Plaintiffs neither expected nor sought a jury with respect to their nuisance abatement claim. What

on September 30, Plaintiffs provided three supplemental tables to Prof. Liebman's expert report and one supplemental table to the Prof. McGuire's report. *See* **Ex. 4** [supplemental tables]. The supplemental table to the McGuire report presents a computation of damages since the time of his original report as well as future damages,[12] while the supplemental tables to the Liebman report assess the overlap between future damages and abatement. Plaintiffs have offered to provide Profs. Liebman and McGuire for deposition to answer questions about the computations in these tables. Plaintiffs do not seek to introduce new experts or new reports – rather, their "new" evidence consists solely of a single table that projects Plaintiffs' past damages into the future (as Prof. McGuire explained in his March, 2019 report could be done) and three tables that show how future damages can be subtracted from the amount needed for abatement. These tables simply extend the methodologies already found by this Court to be reliable.

Defendants seek specifically to exclude testimony based on these supplemental tables, but their arguments are unpersuasive and should be rejected. Plaintiffs had no advance knowledge that the trial would be bifurcated and thus had no reason to separate their future damages from their abatement plan. Once they learned of the bifurcation plan, they promptly supplemented their experts' reports. Rule 26(e) requires that a party supplement its disclosures "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect. . . ." FED. R. CIV. P. 26. Here, Plaintiffs learned that their disclosures were incomplete when they learned that, because of the bifurcated structure of the trial, Prof. Liebman's abatement plan could not be presented to the jury for its consideration in assessing future damages. They provided the supplemental tables less than one week after the Court ruled that it would, in fact, bifurcate the trial. This constitutes a timely supplement.

Even if the Court concludes that the supplemental tables were not timely under Rule 26(e), the tables should still not be struck or excluded because any delay was both "substantially justified"

Plaintiffs did expect was that all of their damages evidence would be submitted in a single proceeding.

[12] The computations in Prof. McGuire's supplemental table are based on the corrected numbers from his errata, rather than the numbers in his original report.

and also is harmless. *See* FED. R. CIV. P. 37(c)(1). Untimely disclosure does not automatically warrant preclusion. Rather, Rule 37 provides that a party may be precluded from using material that was not timely disclosed "unless the failure was substantially justified or is harmless." Either ground is sufficient, under Rule 37, to preclude the sanction of exclusion Defendants seek, but in this instance, both factors are present.

In assessing whether a late disclosure is substantially justified or harmless, the Sixth Circuit uses a five-factor test: "(1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence." *Howe v. City of Akron*, 801 F.3d 718, 748 (6th Cir. 2015). All of these factors weigh in favor of admitting the supplemental tables.

First, as discussed above, the surprise to the Defendants is limited because Defendants have known for eleven months that Plaintiffs are seeking future damages and have had other disclosures, including the testimony of fact witnesses and the original disclosures of Profs. Liebman and McGuire on that subject. Second, to the extent Defendants were surprised by the supplemental tables, that surprise can be readily cured by brief pretrial examination of each of the witnesses, limited to questioning about the supplemental tables. Third, the evidence will not disrupt the trial because Prof. McGuire, who provides the future damages information, will testify to the Counties' past damages in any event. The only question is whether he will also be permitted to explain how his past damage numbers may be extrapolated to calculate future damages. Moreover, the supplemental tables do not alter Defendants' overall exposure at trial. The future damages shown on Prof. McGuire's supplemental table are less than the cost of the abatement plan covering the same period and there would be an offset to prevent double recovery. Thus, although the supplemental table permits a jury to identify future damages separate and apart from the cost of abatement, it does not affect the total amount Plaintiffs are seeking to recover. Fourth, the evidence is important because with information from the Liebman abatement plan, the jury may lack sufficient guidance about the nature of future expenditures. Finally, as discussed above, Plaintiffs

have explained the reason for the late disclosure of these supplemental tables. For these reasons, the disclosure of the supplemental tables on September 30 was both substantially justified and, in light of Plaintiffs' offer to provide the witnesses for additional deposition, harmless. Defendants' motion to exclude them should be denied.

2. <u>Defendants' Omnibus MIL No. 2</u>: The Court should preclude Plaintiffs from offering individualized evidence concerning prescriptions, shipments, and other matters on which they successfully avoided discovery by claiming it was "irrelevant."

Defendants' Omnibus MIL No. 2 is an improper attempt to sanitize the record of all evidence of individual prescriptions, shipments, or use of prescription opioids. This request sweeps far too broadly by conflating the disputed relevancy of individual prescriptions or shipments to *causation* with the relevancy of the very existence of these prescriptions or shipments. The Court's rulings only limited the former, while also *requiring* Plaintiffs, at Defendants' demand, to either identify individual prescriptions and individuals or to forego presentation of evidence at trial. Plaintiffs identified the prescriptions and produced associated claims data, and this Court confirmed the propriety of Plaintiffs' responses in Discovery Rulings 13 and 18. Defendants cannot now categorically exclude this evidence that they demanded be produced.

The Court's discovery rulings that Defendants rely upon for this request did not prohibit all use of individualized evidence or declare it *per se* irrelevant. Just the opposite, in what Defendants call the "seminal" ruling on this subject, *see* Dkt. #2661 at p. 6, the Special Master ruled that:

> Plaintiffs must now produce all available statistical and aggregate evidence, *and enough supporting particulars* to allow the Court and Defendants and the parties' experts to understand the fundamental bases for those statistics and aggregated data; but Plaintiffs need not produce *all* discovery regarding *every* patient or *every* opioid prescription.
>
> ***
>
> Plaintiffs . . . must produce to defendants all relevant aggregated data and statistics. Plaintiffs must also undertake a good faith effort to produce sufficient supporting particularized evidence to allow Defendants and their experts to understand the fundamental bases for these statistics and aggregated data. . . . When Plaintiffs later

> seek *to prove causation or damages at trial . . . Plaintiffs may not rely affirmatively or defensively on any evidence or data they did not produce during discovery.*

Dkt. #606 (Discovery Ruling No. 1) at pp. 4-5 (first and last emphases added; middle emphases in original). This discovery ruling thus both required Plaintiffs to produce some (though not all) individual prescription and shipment evidence and then limited their use of individualized evidence at trial only by holding that they cannot prove causation or damages with evidence not produced during discovery. This ruling is far narrower than the blanket exclusion of individual prescription or shipment evidence Defendants now seek.

And Defendants' request seemingly ignores Plaintiffs' interrogatory responses served during discovery, which were presented to the Special Master at least three times for rulings. In the first ruling, the Special Master ordered Plaintiffs to identify certain medically unnecessary prescriptions and individuals harmed by prescriptions, ruling:

> The plaintiffs' objections are upheld in part, to the extent that plaintiffs do not have to identify ***all*** prescriptions and ***every*** person, as requested in the Interrogatories. Rather, the Special Master rules that plaintiffs must respond to the five Interrogatories at issue ***as rewritten below***.

Dkt. #1027 (Discovery Ruling No. 5) at pp. 1-2 (emphasis in original). The ruling rewrote the interrogatories to replace the phrase "all prescriptions" with "500 prescriptions," and included other criteria (*e.g.*, 10 prescriptions per manufacturer, etc.). *Id.* at pp. 2-3. Plaintiffs objected to this ruling, and the Court modified it as follows:

> Instead of answering the disputed interrogatories as required by the Discovery Ruling, Plaintiffs may instead elect not to answer them ***on the condition*** that Plaintiffs instead categorically and affirmatively respond to the disputed interrogatories by stating that: (1) they will not assert, either in expert opinions or factual presentations at trial, that any specific prescriptions 'were unauthorized, medically unnecessary, ineffective, or harmful' or that 'the filling of [any specific prescriptions] caused or led to harm for which [Plaintiffs] seek to recover,' and (2) Plaintiffs instead will rely, at trial and in expert opinions, solely on a theory of aggregate proof.

Dkt. #1047 at pp. 1-2 (emphasis in original) (internal footnote omitted).

Plaintiffs in fact did produce individual prescription evidence pursuant to the Court's Orders and at Defendants' demand, as follows:

- Manufacturer Interrogatory No. 6 (*identify 500 prescriptions written in reliance on alleged wrongdoing*): Plaintiffs answered that *all* prescriptions in their respective jurisdictions were influenced by Defendants' deceptive marketing, while reaffirming their intent not to assert that any specific prescription caused or led to Plaintiffs' harms;

- Manufacturer Interrogatory No. 7 (*identify 300 persons who became addicted or were harmed as a result of any opioid prescription*): Plaintiffs identified 300 such persons, while reaffirming their intent not to assert that any specific prescription caused or led to Plaintiffs' harms;

- Manufacturer Interrogatory No. 10 (*identify 500 prescriptions that were unauthorized, medically unnecessary, ineffective, or harmful*): Plaintiffs identified more than 500 such prescriptions, and produced over a million lines of corresponding claims data for those patients, while reaffirming their intent not to assert that any specific prescription caused or led to Plaintiffs' harms;

- Pharmacy Interrogatory No. 2 (*identify 500 prescriptions alleged to support claims*): Plaintiffs identified more than 500 such prescriptions, and produced over a million lines of corresponding claims data for those patients, while reaffirming their intent not to assert that any specific prescription caused or led to Plaintiffs' harms;

- Pharmacy Interrogatory No. 3 (*identify 500 prescriptions which caused or led to harm*): Plaintiffs identified 500 such prescriptions, and produced over a million lines of corresponding claims data for those patients, while reaffirming their intent not to assert that any specific prescription caused or led to Plaintiffs' harms.

Dkt. #1058 (Bellwether Plaintiffs' Submission in Response to Discovery Ruling No. 5) at pp. 2-6.[13]

Defendants, having demanded and obtained individual-level prescription evidence from Plaintiffs, cannot now turn tail and preclude all use of such evidence at trial.[14] Nor may Defendants preclude Plaintiffs' use of this evidence on the ground that it is "cherry-picked." Dkt. #2661 at

[13] In late October and mid-November of 2018, Plaintiffs served interrogatory responses that identified prescriptions in response to some, but not all of the interrogatories. Defendants challenged Plaintiffs' responses. On December 22, 2018, the Special Master ordered Plaintiffs to choose between answering all five of the interrogatories fully, or electing not to answer them at all. Dkt. #1215 (Discovery Ruling No. 13) at p. 6. In that same ruling, the Special Master rejected Defendants' complaint that Plaintiffs had not sufficiently identified the alleged misstatements that led to the prescription. *Id.* at p. 7. On December 31, 2018, Plaintiffs amended their responses to identify prescriptions and individuals in response to *all five* interrogatories, in compliance with the Special Master's order. Defendants once again challenged Plaintiffs' response, and the Special Master rejected their challenge in his Discovery Ruling No. 18. Dkt. #1476.

[14] Plaintiffs also have produced millions of lines of information associated with individual prescriptions. For example, pursuant to the Order Regarding Production of Medical and Pharmacy Claims Data in Track One Cases (Dkt. #1421), Plaintiffs produced claims data for: (i) all individuals who received prescriptions Plaintiffs' identified as "medically unnecessary" in response to the interrogatories; and (ii) all individuals insured through the bellwethers who received an opioid prescription.

pp. 8-9 ("This bar should apply to *all* individualized evidence plaintiffs might offer in these categories, including the limited samples they cherry-picked for disclosure in discovery . . . .") (emphasis in original). The Court specifically ruled in Discovery Ruling No. 5 that Plaintiffs did *not* have to produce *all* prescriptions and identify *every* person in response to Defendants' interrogatories. Moreover, Defendants have subpoenaed insurers seeking production of claims data for all residents of Summit and Cuyahoga counties. Defendants thus already have the information they need.

Similarly, Plaintiffs identified suspicious orders or shipments throughout discovery. Discovery Ruling No. 7 directed Plaintiffs to identify suspicious orders, and Plaintiffs did so. In Discovery Ruling No. 12, the Court rejected Defendants' attempt to compel further answers, but directed Plaintiffs to identify additional suspicious orders, which Plaintiffs did. Further, the expert reports of James Rafalski, Craig McCann, and Lacey Keller all identified suspicious orders and the methodology used to identify the orders. The Court denied Defendants' motions to exclude these expert opinions, and those decisions are dispositive of this issue. Dkt. #2492; Dkt. #2494.

In sum, the Court limited but did not prohibit use of individual-level opioid prescription, shipment, and use evidence and since Plaintiffs produced substantial amounts of this evidence at Defendants' demand, Defendants' Omnibus MIL No. 2 for a categorical exclusion of this type of evidence at trial should be rejected.

3. <u>Defendants' Omnibus MIL No. 3</u>: The Court should preclude testimony from witnesses about personal stories of opioid abuse or related harms to themselves or others.

Defendants' Omnibus MIL No. 3 is another improper attempt to sanitize the record of evidence of individual-level harms from opioid abuse. Defendants repeat through incorporation their incorrect arguments from MIL No. 2 for exclusion of all individual-level opioid prescription, shipment, and use evidence. Dkt. #2661 at p. 9. The Court should reject these arguments for the same reasons set forth above (*supra* at § A.2), *i.e.*, that the Court's prior rulings did not prohibit all use of individual level opioid prescription, shipment, and use evidence and that Plaintiffs produced

substantial amounts of this evidence at Defendants' demand, thus making categorical exclusion at trial impermissible.

The Court also should reject Defendants' argument that Plaintiffs' attempts to prohibit questioning on certain deponents' or their family members' private medical treatment information prohibits *all* testimony about opioid abuse. Dkt. #2661 at p. 9. The examples Defendants cite where Plaintiffs' counsel instructed witnesses not to answer involved questions about the witnesses' own medical treatment. Dkt. #2661-4 at 260:1-9; Dkt. #2661-5 at 346:24-347:1-2; Dkt. #2661-6 at 181:7-182:5. Defendants acknowledge, however, that they also obtained testimony about some individuals' use of opioids. Dkt. #2661 at p. 9 n.7. Defendants again therefore cannot categorically preclude all use of this type of evidence at trial.

Nor may Defendants obtain a blanket preclusion on "foundational and hearsay grounds." Dkt. #2661 at p. 10. These are context-specific objections that should be raised and ruled upon not in a vacuum, but with respect to particular evidence if and when it is introduced. *See*, *e.g.*, *Jacobs v. Tricam Industries, Inc.*, 10-11469, 2013 WL 950969, at *2 (E.D. Mich. Mar. 12, 2013) ("[I]t is premature to rule on Plaintiffs' motion prior to Plaintiffs establishing their proofs at trial and before the Court can consider and resolve any evidentiary issues regarding foundation, relevancy, jury confusion, and potential prejudice."); *KCH Services, Inc. v. Vanaire, Inc.*, CIV.A. 05-777-C, 2010 WL 3245243, at *1 (W.D. Ky. June 2, 2010) ("[T]he defendants' motion in limine to exclude documents or require authentication and foundation prior to admission (R. 340) is DENIED as premature.").

Finally, the Court also should reject Defendants' argument that this testimony should be categorically excluded because the witnesses are not parties. Dkt. #2661 at p. 10. A non-party witness may be a source of relevant evidence. *See*, *e.g.*, *Stringer v. N.F.L.*, 749 F. Supp. 2d 680, 704 (S.D. Ohio 2010) ("[W]here an employee is injured while using a product at work, Minnesota courts have held that a third party's conduct is both relevant and sufficient to establish causation on a failure-to-warn claim."). Whether a particular non-party witness's testimony is founded, relevant, and/or fairly or unfairly prejudicial should, again, be raised and decided not in a vacuum, but with

respect to particular evidence if and when it is introduced at trial. *See*, *e.g.*, *Jacobs*, 2013 WL 950969, at *2; *KCH Services*, 2010 WL 3245243, at *1.[15]

For all of these reasons, the Court should deny Defendants' Omnibus MIL No. 3 as both substantively incorrect and procedurally premature.

4. Defendants' Omnibus MIL No. 4: The Court should exclude lay and hearsay testimony about prescription opioids being a "gateway" to illicit opioid use.

Defendants, having failed in their attempt to exclude expert testimony about the Gateway Effect, now attempt to exclude the particularly important testimony on that subject from Thomas Gilson, the Cuyahoga County Medical Examiner.[16] However, Defendants' MIL No. 4 completely omits reference to Dr. Gilson's extensive and ground-breaking demonstration of the Gateway Effect with actual data that he reviewed in his official capacity as Medical Examiner. Defendants' arguments, which do not address this important factual evidence, are insufficient to exclude it.

The Gateway Effect, which refers to the transition from prescription opioids to illicit drugs such as heroin/fentanyl, is a widely acknowledged phenomenon in both scientific literature and common understanding. *See, e.g.,* Dkt. #2197 (Plaintiffs' Opp. to Defendants' Gateway *Daubert* Motion). While the Gateway Effect has been a proper subject of scientific literature and may be addressed by expert testimony, as the Court found in denying the Defendants' *Daubert* motion (Dkt. #2518), the admissibility of expert testimony does not render factual testimony on the issue

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[15] Notably, during discovery, Plaintiffs argued that individual prescription records should not be produced because those individuals were not parties and had not put their treatment at issue or consented to disclosure. Defendants vehemently opposed Plaintiffs' position, and each Defendant sought interrogatory responses, for example, on individuals harmed by opioid prescriptions, which Plaintiffs provided. *Supra* at § A.2. Defendants cannot have it both ways by now seeking to categorically preclude as irrelevant evidence they previously and successfully argued was relevant.

[16] Plaintiffs do not plan to call Jerry Craig, Executive Director of Summit County's Alcohol and Mental Health Board, or Keith Martin, Assistant Special-Agent-in-Charge of the DEA's Cleveland Field Office, to testify in the upcoming trial. Accordingly, Defendants' Omnibus MIL No. 4 is moot as to these witnesses. Plaintiffs note, however, that both of these witnesses appear on Defendants' witness lists. To the extent Defendants call them at trial, these witnesses are certainly permitted to testify as to their factual knowledge arising from their personal experiences and any objections should be assessed in the context of their overall testimony.

irrelevant or inadmissible. Instead, Dr. Gilson's testimony complements and reinforces the opinions of Plaintiffs' experts concerning the pathway from prescription opioids to heroin/fentanyl and provides direct and specific experience of this effect in Cuyahoga County.

On January 14, 2019, Dr. Gilson testified at a deposition in this case. His testimony established that, in his capacity as Medical Examiner, he reviewed Cuyahoga County records that identified heroin/fentanyl as cause of death, and then investigated the Ohio Automated Rx Reporting System (OARRS), a State-wide prescription monitoring database, to determine which of these heroin/fentanyl decedents had prior opioid pain reliever prescriptions. Dr. Gilson "cross-check[ed] our heroin overdoses against the OARRS database," due to a "spike in heroin mortality, and the function of going back to look at that was to firm up, to our satisfaction, that this was in fact, the relationship." Dkt. #2163-2 (1/14/19 Gilson Dep.) at 176:7-177:10. Dr. Gilson testified: "We identified, through our Poison Death Review Committee, through our task forces, that there was a role for the prescription opiates in the subsequent evolution into heroin and fentanyl addiction…" *Id.* at 163:9-164:18. Dr. Gilson and his staff "collected good data to make that association," and, as a result, "We were one of the first counties to recognize is [sic] that *people are going from OPRs [opioid pain relievers] to heroin*." *Id.* at 170:1-171:12; 173:2-174:3 (emphasis added). At Dr. Gilson's second deposition session on January 22, 2019, defense counsel inquired at length about the OARRS program, and Dr. Gilson reiterated that the OARRS data was used to verify the sequence of prior prescription opioids and subsequent fatal overdoses on heroin or fentanyl.[17] These facts are relevant, admissible, and supportive of the opinions of Plaintiffs' experts, previously found to meet *Daubert* standards by this Court.

Defendants raise a red herring as to whether Dr. Gilson's testimony constitutes "expert" opinion, and further misrepresent his qualifications. Plaintiffs maintain that the testimony referenced above constitutes reliable, relevant *factual* evidence of the transition from OPRs to

[17] Dkt. #1977-16 (1/22/19 Gilson Dep.) at 127:5 – 146:8; *see especially*, 132:8-133:4 and 135:1-15 which affirm the use of OARRS data to confirm the factual sequence of opioid pain relievers followed by heroin/fentanyl overdose.

heroin/fentanyl in Cuyahoga County. However, to the extent that qualifications are at issue, Dr. Gilson testified in response to a direct question at his deposition that he is an expert on "the opioid crisis."[18] The fact that he is an expert on this subject in no way impairs the admissibility of his testimony regarding the facts regarding the prior use of opioid prescriptions by heroin/fentanyl decedents. Under Federal Rule of Civil Procedure 26, "[t]he relevant inquiry is the nature of the testimony rather than the status of the witness." FED. R. CIV. P. 26, Commentary; *Jones v. Pramstaller*, No. 1:09-CV-392, 2013 WL 12249827, at *1 (W.D. Mich. Jan. 14, 2013) (holding that where witnesses had both factual and expert knowledge, expert disclosure rules would not apply if the witness would "present eyewitness testimony" rather than expert testimony). Accordingly, "[t]he fact that an individual has expertise does not require him to be disclosed as an expert so long as his testimony is going to be limited to that of a fact witness." *Id.*; *see also Gomez v. Rivera*, 344 F.3d 103 (1st Cir. 2003) (overturning exclusion of testimony of "fact witness" with specialized knowledge, finding the definition of an expert under Rule 26 "does not encompass a percipient witness who happens to be an expert"). There was no need for an expert report to testify as to factual evidence regarding heroin/fentanyl deaths among OPR users in Cuyahoga County. Nor can Defendants claim unfair surprise, since their own counsel asked whether Dr. Gilson held himself out as an expert on opioids and inquired at length on the very topic they now seek to exclude.

Defendants' changing position as to Dr. Gilson's testimony is particularly ironic. As the Court may recall, Defendants affirmatively cited and relied on an outdated version of Dr. Gilson's views on the Gateway Effect in their misleading reference to his 2014 article stating that "there is a dearth of firm evidence establishing the role of OPR [opioid pain relievers] as a gateway to heroin."

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[18] Dkt. #2163-2 (1/14/19 Gilson Dep.) at 103:12-20. Defendants' reference to Dr. Gilson's testimony at his January 22, 2019 deposition is misleading, in that Dr. Gilson was asked only about opioids and their pharmacologic properties, rather than about the "opioid crisis." As to the latter, Dr. Gilson has published articles in scientific journals, and his employment on the opioid crisis would qualify him as an expert. Such expertise is not necessary to admissibility of the factual testimony about the OARRS database/death certificate evidence of prescription opioid use before heroin/fentanyl overdose; nevertheless, it is worth noting that Defendants' motion misstates Dr. Gilson's qualifications and testimony.

Dkt. #1857-1, at pp. 5-6. However, as pointed out in Plaintiffs' Opposition to the *Daubert* motion, Defendants had failed to inform the Court that Dr. Gilson published a follow-up article in 2017, which stated: "While this crisis appears to have its *roots in the overprescribing of opioid pain relievers (OPR)*, more recent years have seen *a transition to illicit drugs*, primarily heroin and fentanyl."[19] Having cited Dr. Gilson's statements on the Gateway Effect when they believed them to support their position, Defendants are in a poor position to seek to exclude his testimony when it turns out that their earlier reliance was misplaced.

Dr. Gilson's 2017 article also states, "The Cuyahoga County Medical Examiner's Office (CCMEO) has a *statutory responsibility* to investigate all deaths that are unnatural, suspicious, or involve the sudden, unexpected death of a person in apparent good health."[20] Dr. Gilson's review pursuant to statute confers the status of public records upon the work product of his office. Dr. Gilson also reviewed the official records found in the OARRS, and those records provided data summarized in his article (*id.*), as well as those described in his deposition testimony, above. These reports are official records, and testimony about them is admissible under FED. R. EVID. 803(6) (Records of Regularly Conducted Activity) and/or 803(8) (Official Records).[21] Dr. Gilson may

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19 Dkt. #2197-29 (T. Gilson, *et al. The Evolution of the Opiate/Opioid Crisis in Cuyahoga County.* Acad. Forensic Pathology) 7:41-49, at p. 42 (2017) (emphasis added); Dkt. #2197 (Plaintiffs' Gateway *Daubert* Opposition Brief) at pp. 20-21.

20 Dkt. #2197-29 at p. 42 (emphasis added). "All DRD in our jurisdiction underwent intensive case review and from 2011 through the third quarter of 2016 (with full-year projections where appropriate), cases were analyzed for basic demographic information (i.e., age, gender, race) and residency status (i.e., urban vs. suburban). More recent years (2015 and 2016) were also analyzed for education level and occupation based on death certificate entries for these variables. The more recent DRD were further stratified by lethal intoxicant represented by heroin, fentanyl, cocaine, OPR, and all others. In our earlier study, we used oxycodone data as a surrogate for OPR, as this has been the major driver of OPR trends in our region [citation omitted]. *Id.*

21 *See State v. Toudle*, 2013-Ohio-1548, ¶ 20 ("[W]e find that an OARRS report is an official record of the state pharmacy board and is admissible under Evid.R. 803(8)."); OHIO REV. CODE ANN. § 313.10 (designating records of coroners, including medical examiners, as public records, with some exceptions); *Stanton v. Vasbinder*, No. 06-10432, 2009 WL 996955, at *10 (E.D. Mich. Apr. 13, 2009) ("[T]he factual observations in a medical examiner's autopsy report have sufficient 'indicia of reliability' to be admitted as a business record regardless of whether or not the examining pathologist testifies at trial."); *Miles v. Scutt*, No. 07-15068, 2008 WL 2949240, at *4 (E.D. Mich. July 29, 2008) (noting that "autopsy reports are business records" and are therefore admissible); *State v. Craig*, 110 Ohio St. 3d 306, 322, 853 N.E.2d 621, 639 (2006) (same).

testify to the evolution of these reports during the course of his tenure, showing the transition from prescription opioids to illicit heroin/fentanyl, as stated in the records kept pursuant to statute. Supplementing his deposition testimony, Dr. Gilson's article shows that prescription opioid mortality peaked in 2011, and that there was an inflection point from that year forward, in which heroin deaths rose and surpassed the declining numbers of prescription opioid deaths in Cuyahoga County, followed by a fentanyl spike beginning in 2014. Dkt. #2197-29 at p. 43, Figure 1. Dr. Gilson's article cites a trend toward lower numbers of death cases of patients with an opioid prescription within the preceding year, suggesting the possibility that "addicts may be circumventing the previously *well-established progression route from OPR to illicit drugs like heroin and fentanyl*." *Id.* at p. 48 (emphasis added). This progression was "well-established" by the factual data evaluated by Dr. Gilson, as summarized above.

For these reasons, Defendants' Omnibus MIL No. 4 should be denied as to Dr. Gilson, and denied as moot as to Mr. Craig and Mr. Martin.

5. <u>Defendants' Omnibus MIL No. 5</u>: The Court should preclude evidence concerning lobbying and other protected petitioning activity.

As a preliminary matter, Plaintiffs dispute the underlying premise of Defendants' argument in support of this MIL (*i.e.*, that the lobbying and petitioning activities at issue in this case are constitutionally protected). It is well-established that neither the First Amendment nor the *Noerr-Pennington* doctrine immunizes fraud.[22] Regardless, Plaintiffs have clearly stated that they are not

[22] *See, e.g., Illinois, ex rel. Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 606, 612 (2003); *Cal. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513-15 (1972); *Wise v. Zwicker & Associates, P.C.*, 780 F.3d 710, 719 n.5 (6th Cir. 2015); *Potters Med. Ctr. v. City Hosp. Ass'n*, 800 F.2d 568, 580 (6th Cir. 1986). Defendants claim the fraud exception to *Noerr-Pennington* applies only in the context of an adjudicatory proceeding (Dkt. #2661 at p. 14 n.13). But at least some of Defendants' fraudulent communications with the government were made in an adjudicatory context, such as during enforcement-related proceedings or rulemakings. Additionally, the DEA's quota-setting process is unquestionably adjudicatory in nature, as it conducts public hearings, accepts evidence and argument from interested parties, makes findings of fact and conclusions of law, and its actions are guided by enforceable standards subject to review (21 C.F.R. §§ 1303.11 – 1303.13, 1303.31 – 1303.37, 1316.41 – 1316.68; 5 U.S.C. §§ 551-559; 21 U.S.C. §§ 826, 877). *Cf. Kottle v. N.W. Kidney Centers*, 146 F.3d 1056, 1062 (9th Cir. 1998) ("The CON determination by the Department [of Health] bears many indicia of a true adjudicatory proceeding. The Department conducts public hearings, accepts written and oral arguments, permits representation by counsel, and allows affected persons to question witnesses. The Department must

attempting "to impose liability upon the Defendants for their lobbying or petitioning activities, nor do [they] argue that these activities were unlawful conduct." Dkt. #2090-1 at p. 3; Dkt. #2562 at p. 6 n.7. Thus, the question of whether or not these activities are constitutionally protected need not be decided here.[23]

Even assuming, *arguendo*, that Defendants' lobbying and petitioning conduct is constitutionally protected such that those activities could not directly give rise to liability, this does not mean evidence of that conduct is inadmissible at trial. Far from it. Rather, the United States Supreme Court, and courts throughout the country, have recognized that such evidence is still relevant and admissible to show the purpose and character of Defendants' wrongful activities. *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 n.3 (1965) ("It would of course still be within the province of the trial judge to admit this evidence, if he deemed it probative and not unduly prejudicial, under the 'established judicial rule of evidence that testimony of prior or subsequent transactions, which for some reason are barred from forming the basis for a suit, may nevertheless be introduced if it tends reasonably to show the purpose and character of the particular transactions under scrutiny."); *In re Welding Fume Products Liab. Litig.*, 1:03-CV-17000, 2010 WL 7699456, at *93 (N.D. Ohio June 4, 2010) ("*Welding Fume II*") (noting that it previously declined to

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issue written findings after its hearing. Its decision is appealable, and that appeal is governed by APA procedures and statutory standards. In all, we believe that this combination of facts makes the application of the judicial sham exception appropriate in this case."); *DeLoach v. Philip Morris Companies, Inc.*, 1:00CV01235, 2001 WL 1301221, at *12 (M.D.N.C. July 24, 2001) (no *Noerr-Pennington* immunity for defendants who intentionally submitted false purchase intentions to the USDA that resulted in lower annual tobacco quotas).

[23] Although Plaintiffs are not seeking to impose liability on Defendants for their petitioning conduct, Plaintiffs do not waive any argument they may have at trial that certain petitioning conduct of Defendants is not constitutionally protected under the First Amendment or the *Noerr-Pennington* doctrine. Plaintiffs also do not concede that the *Noerr-Pennington* doctrine applies outside the antitrust context. Although the Sixth Circuit recognizes that other federal courts have applied the doctrine to common law claims, it has not yet definitively resolved the issue. *See Campbell v. PMI Food Equip. Group, Inc.*, 509 F.3d 776, 790 (6th Cir. 2007) (acknowledging other federal courts have applied *Noerr-Pennington* to common law claims, but stating that it "need not decide that issue here because the Workers failed to state such a claim"); *see also DIRECTV, Inc. v. Cavanaugh*, 321 F. Supp. 2d 825, 840 (E.D. Mich. 2003) ("Since the current dispute is not regulated by the Sherman Act, the Court is reluctant to apply the *Noerr–Pennington* doctrine.").

issue a pretrial, blanket ruling excluding all evidence of the defendants' lobbying activities, and in fact had "admitted several such documents over defendants' objection because, even though the document was arguably created for lobbying purposes, it also contain[ed] statements directly relevant to issues central to every *Welding Fume* case").[24] For example, such evidence demonstrates

[24] *See also Telecor Commun., Inc. v. S.W. Bell Tel. Co.*, 305 F.3d 1124, 1136-39 (10th Cir. 2002) (district court did not abuse its discretion admitting evidence of defendant's misleading statements to Oklahoma Corporation Commission where offered "for the proper purpose of supporting the claim that [the defendant] acted for an improper monopolistic purpose"); *Alexander v. Natl. Farmers Org.*, 687 F.2d 1173, 1196 (8th Cir. 1982) ("Exempt conduct may be considered, however, to the extent it tends to show the 'purpose or character' of other, nonexempt activity. Here, the district court's findings are noteworthy because they show CMPC, AMPI and Mid-Am acting in concert with the specific intent to block NFO from competing as a qualified cooperative. While not illegal because of the exemption, this conduct does have evidentiary value as to the purpose and concerted character of these co-ops' contemporaneous nonexempt activities.") (internal citations omitted); *Cipollone v. Liggett Group, Inc.*, 668 F. Supp. 408, 410-11 (D.N.J. 1987); *Gillis v. Murphy-Brown, LLC*, 7:14-CV-185-BR, 2018 WL 5928010, at *1 (E.D.N.C. Nov. 13, 2018) (noting that the *Noerr-Pennington* doctrine does not operate "in the manner in which defendant seeks to do here—[to] bar otherwise admissible evidence in a state law private nuisance lawsuit"); *In re Testosterone Replacement Therapy Products Liab. Litig. Coordinated Pretrial Proceedings*, 14 C 1748, 2018 WL 305503, at *10 (N.D. Ill. Jan. 6, 2018) ("The Court disagrees that the *Noerr–Pennington* doctrine is applicable. Nolte does not seek to hold AbbVie *liable* for its alleged petitioning activity; he intends to offer evidence of that activity to demonstrate AbbVie's motive or intent. There is no general rule that evidence of activity that is protected by the First Amendment—speech, for example—is inadmissible.") (internal citation omitted); *In re Volkswagen "Clean Diesel" Mktg., Sales Practices, and Products Liab. Litig.*, MDL 2672 CRB (JSC), 2017 WL 4890594, at *15 n.4 (N.D. Cal. Oct. 30, 2017) ("The *Noerr-Pennington* doctrine does not bar consideration of Bosch's lobbying activities. . . . Here, the Franchise Dealers are not asserting that Bosch's lobbying activity was unlawful. Instead, they contend that Bosch's lobbying activity proves its knowledge of, and intent to participate in, the emissions fraud."); *In re: Gen. Motors LLC Ignition Switch Litig.*, 14-MD-2543 (JMF), 2015 WL 8130449, at *1-2 (S.D.N.Y. Dec. 3, 2015) ("Under the *Noerr-Pennington* doctrine, a defendant may not be held liable based solely on conduct that is protected by the First Amendment, but that does not mean that such conduct is altogether inadmissible or necessarily lacking in evidentiary value."); *Community Action League v. City of Palmdale*, CV 11-4817 ODW VBKX, 2012 WL 10647285, at *8 (C.D. Cal. Feb. 1, 2012); *Wolfe v. McNeil-PPC, Inc.*, CIV.A. 07-348, 2012 WL 38694, at *6 (E.D. Pa. Jan. 9, 2012) (rejecting defendants' argument that the *Noerr-Pennington* doctrine compelled the exclusion of evidence of two citizen's petitions one defendant submitted to the FDA and noting that the petitions were "relevant to defendants' knowledge regarding the safety of ibuprofen and the adequacy of its labeling"); *Adams v. U.S.*, 03-0049-E-BLW, 2009 WL 1259019, at *2 (D. Idaho May 3, 2009) (denying motion *in limine* to exclude evidence of defendant's communications with the EPA under *Noerr-Pennington* because, among other things, such evidence was "relevant to plaintiffs' claims of misbranding and failure to warn, and shows the state of [the defendant's] knowledge which is relevant to many claims"); *Confederated Tribes of Siletz Indians of Oregon v. Weyerhaeuser Co.*, CV 00-1693-PA, 2003 WL 24901381, at *7 (D. Or. July 5, 2003) ("[E]ven if the state lands transaction could not itself have been a basis for liability [under *Noerr-Pennington*], evidence regarding that transaction would likely have been admissible for other purposes, such as showing market share, the extent of any log sources available to competitors, the scope of the relevant market or markets, the manner in which Weyerhaeuser allegedly obtained and maintained its monopoly, the company's motives and intent, and to impeach credibility").

Defendants' knowledge and intent to participate in a RICO enterprise.[25] For these reasons, courts regularly deny motions *in limine* seeking to preclude evidence of lobbying and petitioning activities.[26]

Moreover, evidence of Defendants' lobbying activities will be particularly probative in this case since Defendants, as they have already indicated, plan to argue that the DEA did not do enough to enforce the law. Plaintiffs are entitled to rebut this argument with evidence that, for example, Defendants and their trade association (i) lobbied to limit the DEA's enforcement authority, and (ii) influenced their Congressional allies to criticize the DEA in order to undermine the agency's authority and effectiveness.

Defendants' cases do not support granting their *limine* request. First, they cite *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014), for the proposition that "[a]llowing evidence of such petitioning activity to be presented in litigation inherently chills the exercise of that right." Dkt. #2661 at p. 13. In *Octane*, which involved the appropriateness of an attorney's fee

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25 *See In re Chrysler-Dodge-Jeep Ecodiesel Mktg., Sales Practices, and Products Liab. Litig.*, 295 F. Supp. 3d 927, 973 n.7 (N.D. Cal. 2018) ("Plaintiffs are not asserting that the Bosch Defendants' lobbying activity was unlawful. Instead, they assert that the lobbying activity helps prove knowledge and intent to participate in the RICO enterprise. Use of the Bosch Defendants' lobbying activity in this manner is not barred by *Noerr-Pennington*."); *Nat.-Immunogenics Corp. v. Newport Tr. Group*, SACV1502034JVSJCGX, 2018 WL 6137597, at *4 (C.D. Cal. May 16, 2018) ("While the evidence may ultimately be inadmissible under the Noerr-Pennington doctrine as a basis for liability, it may be admissible for some other purpose such as to show intent to participate in a RICO enterprise, in which case Noerr-Pennington would not be a bar to admissibility.").

26 *See, e.g., Welding Fume II*, 2010 WL 7699456, at *93; *In re Tylenol (Acetaminophen) Mktg., Sales Practices and Products Liab. Litig.*, 181 F. Supp. 3d 278, 306 (E.D. Pa. 2016) (denying defendants' motion *in limine* to exclude lobbying evidence; "[T]he plaintiff seeks to offer evidence about how the defendants attempted to influence, petition, or communicate with Congress and/or the FDA to show their knowledge, state of mind, or intent. It would be a stretch to say that Noerr-Pennington bars any use of any evidence of the defendants' petitioning of the government, and its agencies, or evidence of any communications with the FDA."); *Cipollone*, 668 F. Supp. at 410-11 (denying defendants' motion *in limine* to exclude evidence that defendants provided false and misleading information to Congress; court deferred decision of "whether the specific evidence to be offered is probative of a continuing course of conduct that corroborates plaintiff's direct allegations" until trial so that it could be "decided in context"); *Testosterone*, 2018 WL 305503, at *10 (denying defendant's motion *in limine* to exclude all evidence of defendant's lobbying efforts with the FDA); *Gen. Motors*, 2015 WL 8130449, at *1-2 (denying defendants' motion *in limine* to exclude evidence that it intentionally misled or concealed information from, or tried to influence, NHTSA); *Wolfe*, 2012 WL 38694, at *6 (denying defendants' motion *in limine* to exclude citizen's petitions submitted to the FDA); *Adams*, 2009 WL 1259019, at *2 (denying motion *in limine* to exclude evidence of defendant's communications with the EPA under *Noerr-Pennington*).

award in a patent litigation case, the Supreme Court briefly discussed the *Noerr-Pennington* doctrine because the plaintiff had attempted (unsuccessfully) to analogize the standard for baseless litigation under that doctrine with the standard applicable under the Patent Act. 572 U.S. at 548, 555-56. The Court noted that it had "crafted the *Noerr-Pennington* doctrine . . . to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances." *Id.* at 556. The case has absolutely nothing to do with the admissibility of petitioning-related evidence.

Defendants then cite *Snyder v. Phelps*, 562 U.S. 443 (2011), to support their argument that "plaintiffs cannot offer evidence of defendants' lobbying efforts to prove conspiracy." Dkt. #2661 at pp. 14-15. But *Snyder* is entirely distinguishable. In that case, the plaintiff asserted various tort claims, including civil conspiracy, against the Westboro Baptist Church and some of its members based on their picketing of a military funeral. 562 U.S. at 447. At trial, the jury found in favor of the plaintiff. *Id.* The Supreme Court affirmed the reversal of the jury's verdict, holding that "the First Amendment shield[ed] the church members from tort liability for their speech in th[at] case." *Id.* at 447, 451-60.[27] Significantly, the defendants' picketing formed the *entire basis* for the plaintiff's tort claims in that case. *Id.* at 447.[28] Because the underlying torts upon which the alleged conspiracy was based failed, the civil conspiracy claim also failed. *Id.* at 460. This case does not address the admissibility of lobbying or petitioning evidence.[29]

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[27] Notably, the Supreme Court noted that none of the defendants' statements were "provably false[.]" *Id.* at 451. And it also emphasized that its holding was "narrow." *Id.* at 460 ("We are required in First Amendment cases to carefully review the record, and *the reach of our opinion here is limited by the particular facts before us*.") (emphasis added).

[28] In the present case, to the contrary, Plaintiffs' claims are based on Defendants' (i) unlawful marketing and distribution of opioids through fraud and misrepresentation, and (ii) unlawful failure to prevent diversion and failure to monitor for, report, and prevent shipment of suspicious orders of opioids. It is the entirety of that wrongful conduct that forms the basis of Plaintiffs' civil conspiracy claims. *See, e.g., Taylor v. AirCo, Inc.*, CV 02-30014-MAP, 2003 WL 27382684, at *16 n.8 (D. Mass. Aug. 4, 2003) (rejecting defendants' argument that they were immune from liability based on their lobbying efforts under *Noerr-Pennington*; "Plaintiffs do not seek to have liability imposed solely on the basis of lobbying efforts. Rather, Plaintiffs allege 'a continuing course of deceptive conduct of which this activity was just one small part.' "), *report and recommendation adopted,* CV 02-30014-MAP, 2003 WL 27382685 (D. Mass. Sept. 26, 2003).

[29] Nor does this case address the *Noerr-Pennington* doctrine at all.

Defendants also claim "the Sixth Circuit prohibits parties from using evidence of lobbying to establish a broader pattern of illicit conduct[,]" citing *City of Cleveland v. Cleveland Elec. Illuminating Co.*, 734 F.2d 1157 (6th Cir. 1984) ("*Cleveland II*") and *City of Cleveland v. Cleveland Elec. Illuminating Co.*, 538 F. Supp. 1257 (N.D. Ohio 1980) ("*Cleveland I*"). Dkt. #2661 at p. 15. Of course neither of these opinions, which arise from the same *antitrust* case,[30] addresses the admissibility of petitioning evidence in cases involving nuisance, RICO, OPCA, or common-law conspiracy claims. Moreover, neither case even stands for the proposition that such evidence is *per se* inadmissible in antitrust cases.

In *Cleveland I*, the City of Cleveland brought an antitrust suit against an electric utility. 538 F. Supp. 1257. There were two trials, the first of which ended in a hung jury. *Cleveland II*, 734 F.2d at 1160. Prior to the second trial, the defendant sought to preclude the plaintiff from "enter[ing] upon a [specific] course of inquiry" in its examination of the "defendant's general attorney, the *sole purpose* of which [wa]s to elicit testimony" that would trigger the introduction of certain *Noerr-Pennington*-protected evidence that the court had *already determined* should be excluded based on the first trial. *Cleveland I*, 538 F. Supp. at 1278 (emphasis added). After noting that the protected conduct of which the plaintiff was seeking to introduce evidence was not relevant to the plaintiff's claims,[31] the court precluded the plaintiff from initiating that course of inquiry unless the defendant opened the door.[32] In other words, the court analyzed specific pieces of evidence of the defendant's *Noerr-Pennington*

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30 It is well established that, subject to certain exceptions, petitioning conduct, even if undertaken for anti-competitive purposes, is not sanctionable *under the Sherman Act*. *See Pennington*, 381 U.S. at 670 ("Joint efforts to influence public officials do not violate antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.").

31 *Id.* at 1279 ("In light of the fact the only instance of protected conduct sought to be introduced herein relates to a lawsuit *which, the City concedes, did not actually affect the construction of the 69KV intertie*, the plaintiff may not inquire as to activity undertaken by CEI which was merely 'designed' to delay, impede, or make more costly the construction of the 69KV temporary emergency interconnection.") (emphasis added).

32 *Id.* at 1279 ("Although plaintiff may not, at this juncture, initiate inquiry designed solely to trigger admission of Noerr-Pennington conduct, the Court recognizes, of course, that the evolution of the defendant's evidence may 'open the door' for the introduction of such conduct, as occurred during the first trial.").

protected conduct, determined that this evidence should be excluded, and then prohibited the plaintiff from questioning a witness in its case-in-chief with the sole purpose of triggering the introduction of the previously-excluded evidence. Contrary to Defendants' assertions otherwise, *Cleveland I* does not support granting Defendants' overly-broad MIL No. 5. In fact, that court explicitly stated that determinations as to the admissibility of petitioning-related evidence *should be deferred until trial*:

> [T]he weighing process embodied in Rule 403, and the similar balancing analysis which governs the admissibility of evidence relating to activities protected by the Noerr-Pennington doctrine, are more appropriately undertaken in the context of the evidence theretofore adduced. To exclude broad categories of evidence in this action, prior to the presentation of any proof, might appear in a controversy of this nature to risk depriving the plaintiff of what may ultimately be demonstrated to be the "legitimate moral force" of its evidence. The Court is thus constrained to conclude that the extent to which the litigants may properly adduce evidence which pertains to the substance of the tendered admission is a matter which must await the actual presentation of proof in this case.

Id. at 1265 (internal citations omitted).[33]

Defendants cite *Cleveland II* as affirming the *Cleveland I* decision (Dkt. #2661 at p. 15), but in actuality *Cleveland II* affirmed the district court's judgment on the jury's defense verdict from the second trial. 734 F.2d at 1160, 1169.[34] The plaintiff appealed, arguing, among other things, that the trial judge erred by refusing to admit into evidence information regarding the defendant's secret sponsorship of a lawsuit challenging an order by the Federal Power Commission requiring the defendant to interconnect with the plaintiff's utility company. *Id.* at 1161-62. The plaintiff claimed the evidence demonstrated the defendant's "anticompetitive intent to exclude [the plaintiff's utility

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[33] The court also recognized that courts are "vested with broad discretion in determining the admissibility of evidence of conduct falling within the protection of the Noerr-Pennington doctrine." *Id.* at 1277.

[34] Defendants also purport to quote certain language from *Cleveland II* in their motion, implying that this was a direct quote by the Sixth Circuit's majority opinion. Dkt. #2661 at p. 15 ("Allowing such questioning would 'gut the constitutional protection afforded under the Noerr-Pennington doctrine and have a 'chilling effect' upon the exercise of First Amendment rights.' *Cleveland Elec. Illuminating Co.*, 734 F.2d at 1171."). In fact, this is a direct quote from the district court in *Cleveland I* (538 F. Supp. at 1279), which is then re-quoted in a parenthetical to a citation to *Cleveland I* in the *dissent* to *Cleveland II*. 734 F.2d at 1171.

company] from the retail electric power market." *Id.* at 1161. The district court ruled that the evidence was "inadmissible on the basis of the *Noerr-Pennington* Doctrine." *Id.* at 1161-62. The Sixth Circuit held that the district court had not abused its discretion in excluding the evidence because the conduct was "not the kind of antitrust activity that is admissible to prove a Sherman Act violation" and the plaintiff's purpose in introducing the evidence "was to show the anticompetitive character and nature of [the defendant's] conduct in this episode as a part of the alleged broader pattern of conduct condemned by the Sherman Act, and to cast appellee and its counsel in the role of deceivers[,]" which was "not an admissible basis for its introduction[.]" *Id.* at 1162-63. The court further noted that the evidence was cumulative because the defendant had already admitted at trial that its objective was "to reduce and *eliminate* competition with its competitor" and the plaintiff had introduced considerable other evidence of the defendant's anti-competitive conduct. *Id.* at 1164. Thus, *Cleveland II,* similar to *Cleveland I*, simply reiterates that the balancing test for whether a particular piece of petitioning-related evidence is admissible requires a fact-specific inquiry that should be deferred until trial.

Defendants' Rule 403 arguments are also without merit. They claim that "evidence of lobbying activity is considered presumptively prejudicial." Dkt. #2661 at p. 15. But the cases they cite for this proposition—all of which, not surprisingly, arise in the antitrust context—are entirely distinguishable. In *U.S. Football League v. Natl. Football League*, 634 F. Supp. 1155 (S.D.N.Y. 1986) ("*U.S. Football I*"), the plaintiffs brought various antitrust claims against the NFL. *Id.* at 1158. The NFL sought summary judgment on certain of these claims that related to the NFL's actions "directed at preventing existing and potential USFL clubs from gaining adequate access to suitable stadium facilities." *Id.* at 1176. The NFL argued that the stadium-related claims were barred under the *Noerr-Pennington* doctrine because the conduct at issue almost entirely consisted of the NFL's lobbying of state and local governments on issues related to stadium lease approvals. *Id.* at 1177-78. The court held that such conduct could not "give rise to liability under the federal antitrust laws." *Id.* at 1180. It recognized, however, that evidence of stadium-related conduct could potentially be "probative of the 'purpose and character' of the transactions" that formed the basis of some of the

plaintiffs' other claims. *Id.* at 1180 (quoting *Pennington*, 381 U.S. at 670 n.3). And it expressly acknowledged that the admissibility of this evidence should be determined *during the trial*: "Since the admissibility or exclusion of such 'purpose or character' evidence will be within this Court's discretion at trial, *it would be premature to rule on such matters at this time*." *Id.* (internal citation omitted) (emphasis added). Despite this acknowledgement, the court proceeded *in dicta* to make some "preliminary observations" regarding the potential admissibility of such evidence at trial. *Id.* The court emphasized the need to weigh the probative value of the evidence against the risk of undue prejudice. *Id.* at 1180-81. The court noted that the evidence was largely irrelevant to the plaintiffs' remaining claims and had significant evidentiary problems, including that most of it was hearsay. *Id.* at 1181 & n.13. It was during this *dicta* analysis that the court stated: "Given such risks, the exclusion of 'purpose and character' evidence consisting of conduct clearly embraced by *Noerr-Pennington* should be the rule rather than the exception *in an antitrust case*." *Id.* at 1181 (emphasis added).[35] But even if the present case was an antitrust case (which it is not), and even if the 33-year-old *dicta* of a district court outside this circuit was binding on this Court (which it is not), *U.S. Football I* does not support granting Defendants' *limine* request. To the contrary, it *reaffirms* Plaintiffs' argument that such determinations should be deferred until trial, where the Court will have the benefit of a developed record in order to analyze whether a specific piece of lobbying-related evidence is admissible. 634 F. Supp. at 1180.

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[35] In their motion, Defendants cite *U.S. Football League v. Natl. Football League*, 842 F.2d 1335 (2d Cir. 1988) ("*U.S. Football II*") as affirming the district court's *U.S. Football I* opinion. Dkt. #2661 at p. 15. In actuality, the Second Circuit's opinion affirmed the district court's denial of the plaintiffs' *post-trial* motions which dealt with issues that arose *during* the trial. *Id.* at 1340-41. In fact, the appellate court noted that the district court's summary judgment ruling "in favor of the NFL on the USFL's stadium-related claims on *Noerr-Pennington* grounds" had "not been appealed." *Id.* at 1350 n.13. The Second Circuit acknowledged that the district judge actually admitted some lobbying evidence at trial, but also held that he had not abused his discretion in excluding certain other lobbying evidence during the trial based on the specific circumstances of that case. *Id.* at 1373-75. Notably, the appellate court did not state that such evidence was "presumptively prejudicial"; rather, it acknowledged that lobbying evidence "may be admitted . . . 'if it tends reasonably to show the purpose and character of the particular transactions under scrutiny,' and that evidence is more probative than prejudicial." *Id.* at 1374 (internal citation omitted); *see also id.* ("Evidence of lobbying may, as we have already stated, nevertheless be admitted as purpose or character evidence.").

In *Feminist Women's Health Ctr., Inc. v. Mohammad*, 586 F.2d 530 (5th Cir. 1978), which is also an antitrust case, the court never said lobbying/petitioning evidence is "presumptively prejudicial." Rather, in determining whether the district court properly granted summary judgment on one of the plaintiff's antitrust claims, the Fifth Circuit acknowledged that "[e]vidence of activity that is protected by the Noerr doctrine may be admitted to show the purpose and character of other activity if doing so is not overly prejudicial to the defendants." *Id.* at 543 n.7. The court determined that a specific piece of petitioning evidence was inadmissible in that case because "[i]ts evidentiary value to the plaintiff [wa]s far outweighed by the defendants' first amendment interests." *Id.* Specifically, the court found that "the probative value of this evidence [wa]s low" because "[a]s evidence of the alleged conspiracy it [wa]s cumulative" and "[a]s evidence of [the defendant's] state of mind it [wa]s exceedingly weak[.]" *Id.* As with *U.S. Football I*, this case does not support the granting of Defendants' broad *limine* request; rather, it reaffirms that the admissibility of lobbying evidence is a fact-specific inquiry that is best reserved for trial.

Finally, *Weit v. Contl. Illinois Nat. Bank and Tr. Co. of Chicago*, 641 F.2d 457 (7th Cir. 1981) is yet another antitrust case in which the appellate court analyzed whether the district court erroneously declined to consider evidence of the defendants' lobbying activities when deciding whether to grant the defendants' summary judgment motion. *Id.* at 458, 466-67. In *Weit*, the plaintiffs alleged that the defendant banks "conspired to fix the interest rate paid by consumer credit cardholders on extended payments[.]" *Id.* at 548. After *eight years* of discovery, the plaintiffs "failed to produce any significant probative evidence to support the[ir] complaint[,]" leading the district court to grant summary judgment in favor of the defendants. *Id.* On appeal, the plaintiffs argued, among other things, that the district court erred by not considering evidence of the defendants' lobbying efforts to influence the passage of a bill in the legislature that would allow the banks to charge an increased interest rate. *Id.* at 461, 466-67. The district court did not exclude that evidence because the conduct was immunized from antitrust liability under *Noerr-Pennington*, but rather because "the prejudicial quality of this evidence outweighed its probative value." *Id.* at 466. The Seventh Circuit held that the district court "correctly excluded this evidence from consideration on

the motion for summary judgment" because such evidence would likely confuse the jury at trial *given the lack of any other evidence of an antitrust conspiracy*:

> We believe that confusion of issues is the probable result of admission of this evidence. *Given the lack of any substantial evidence of an antitrust conspiracy in the instant case*, the threat of prejudice from admission of this evidence is considerable. *The lack of other probative evidence of conspiracy would serve to focus the jury's attention on the lobbying evidence*. This could easily result in a finding of antitrust liability for engaging in the First Amendment right to petition which Noerr-Pennington protects.

Id. at 467 (emphasis added). It was for this reason that the court determined a cautionary instruction would not be sufficient to avoid confusion in that particular case. *Id. See also id.* at 464 ("We simply cannot turn our heads and ignore the practical realities of complex anti-trust litigation. A trial of this nature places a substantial burden on jurors who are seldom prepared to analyze the complexities of anti-trust claims.").

Accordingly, even if certain petitioning conduct of Defendants is immunized under the First Amendment or *Noerr-Pennington*, evidence of that conduct may still be admitted if relevant to Plaintiffs' claims. Defendants have failed to demonstrate that this evidence is clearly inadmissible on all potential grounds. *Jordan*, 2010 WL 4281807, at *1. Defendants' Omnibus MIL No. 5 should be denied.

6. <u>Defendants' Omnibus MIL No. 6</u>: The Court should bar Plaintiffs from introducing evidence of alleged wrongful shipments to places outside Track One jurisdictions.

Defendants seek an order barring admission of evidence and argument concerning wrongful shipment to locations other than Cuyahoga and Summit Counties.[36] They argue that there is no evidence that such shipments had any material impact on Cuyahoga or Summit Counties and therefore there is no basis for their admission at trial. Defendants are wrong on the facts and the law.

[36] This issue is raised by multiple Defendant motions *in limine*, including Defendants' Omnibus Motion *in Limine* (MIL No. 6), Henry Schein's Motion *in Limine* (MIL No. HS-8), and Teva and Actavis's *Motion in Limine* (MIL Nos. TAD-4 and TAD-5).

In fact, there is abundant evidence in the record that the opioids Defendants shipped migrated beyond the borders of the states to which the shipments were made, including, oftentimes, to Ohio, and that Defendants were well aware of this phenomenon.[37] The Ohio Department of Mental Health and Addiction Services was aware of the migration of opioids into Ohio.[38] Defendants were regularly alerted to the migration phenomenon by the DEA,[39] and their personnel acknowledged the reality of diversion and migration in their depositions.[40] With respect to Walgreens, Plaintiffs' expert James Rafalski opined that Walgreens was familiar with the Florida phenomenon in part because its pharmacy managers alerted their supervisors to the high volume of prescriptions coming from out of state:

> Walgreens's also knew opioids it distributed in Florida were migrating into Ohio. Because Walgreens failed to maintain many pre-2012 documents outside of those produced to the DEA during the Jupiter DC investigation, many of the pre-2012 documents Walgreens produced relate to Walgreens distribution in Florida. This information is highly relevant to CT1, however, because not only does the evidence show that Walgreens's distribution failures were "systemic", as noted by the DEA in the 2013 MOA, but the evidence further shows that Walgreens knew and/or should have known that the high-volume Florida prescriptions were traveling out of state, including to Ohio. For example, Pharmacy managers in Florida alerted their supervisors and the distribution center that they were ordering 55+ bottles a week (where 30 bottles was an admitted red flag) and that many of the prescriptions were coming from out of state. Walgreens was well familiar with the "Florida migration"

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37 *See, e.g.,* **Ex. 5** [CAH_MDL_2804_031944472] at p. 118 (vast majority of Florida pain clinic patients came from out-of-state, including Ohio); **Ex. 6** [FTIMDL00039536] (most drug customers travel to Florida from Ohio and elsewhere); **Ex. 7** [HDS_MDL_00455124] (travelers seeking opioids come "by the thousands" to Florida from Ohio and elsewhere); **Ex. 8** [ABDCMDL00360134] at Slide 7(2009 AmerisourceBergen presentation describing distribution from Florida pain clinics to Ohio and other states); **Ex. 9** [MCKMDL00407451] at 465(McKesson presentation depicting "Drug Diversion Migration Out of Florida" to Ohio and elsewhere); **Ex. 10** [WAGMDL00441398—1431] (describing case studies of diverted opioids migrating to Ohio); **Ex. 11** [WAGMDL00049752] at 759 ("this is not just a Florida problem").

38 *See* **Ex. 12** [*Ohio Substance Abuse Monitoring Network Surveillance of Drug Abuse Trends in the State of Ohio*, CUYAH_001656831] at 834, 840, 913, 924 (Cleveland region law enforcement and others note influx of prescription opioids from outside Ohio).

39 *See, e.g.,* **Ex. 13** [CAH_MDL_02448227] at 378—80; **Ex. 14** [US-DEA 00000001 – 141]; **Ex. 15** [WAGMDL00289068] at 153.

40 *See, e.g.*, Dkt. #1962-24 (8/1/18 Hartle Dep.) at 318:24 – 321:2.

> phenomenon, in which prescription opioids were being dispensed in Florida and transported north to states include Ohio, and knew that "Interstate 95 has been renamed the Oxycodone Express because of the brisk travel of people from Kentucky, Tennessee, [and] Ohio to South Florida to obtain medications." When the DEA issued Orders to Show Cause to Walgreens's Jupiter Distribution Center and six Florida Walgreens pharmacies, the DEA specifically noted likely migration to Ohio."

Dkt. #1895-19 (Rafalski Expert Rep.) at p. 121; *see also* Dkt. #1969-19 (5/14/19 Rafalski Dep.) at 552:13-554:6 (testifying as to the basis for his opinion and observing that "by this time period, everybody knew there was a problem in Florida").

Against this robust record of diversion and migration, of which the above-cited materials are only examples, Defendants' assertion of the lack of a nexus between their irresponsible shipment practices and harm to the CT-1 Plaintiffs rings hollow. Defendants shipped tens of millions of opioid pills to resellers throughout the U.S. They knew that those resellers could, and often did, sell those opioids to individuals who had come from Ohio or elsewhere to obtain pills they could in turn sell at a substantial profit back home. That every pill that was diverted posed a risk to localities throughout the nation was not only foreseeable to Defendants, it was observed by them. Each shipment Defendants made in disregard of the potential for diversion is evidence of damages caused by Defendants to localities throughout the nation.

In addition, because the potential for diversion is so great and its consequences so pernicious, each Defendant was required to establish and maintain a suspicious order monitoring ("SOM") program. Plaintiffs have catalogued the numerous flaws in the SOMs operated by Defendants. Dkt. #1895-19 (Rafalski Expert Rep.) at pp. 46-186. Each Defendant's SOM program was implemented nationally; no special procedures were followed with respect to the CT-1 jurisdictions or elsewhere. *See id.* at p. 62 (noting that DEA enforcement actions against Cardinal in Maryland and Florida involved increasing thresholds despite evidence indicating potential diversion, and that these actions identified a systematic problem in Cardinal's nationwide distribution operations); *id.* at p. 79 (observing that the DOJ recognized that there was a "nationwide" and "systemic" failure of McKesson to report suspicious orders and otherwise maintain effective

controls against diversion); *id.* at p. 85 (ABDC's settlement with the DOJ arose from failures in its SOM program, which were systematic because ABDC maintained national SOM policies and procedures); *see also, e.g.*, Dkt. #1971-2 (10/16/18 Stahmann Dep.) at 94-96. Because the SOM programs were implemented nationally, not regionally, each suspicious order filled by Defendants is also evidence of the flaws in Defendants' SOM programs, wherever it shipped to. For this reason, as well, Defendants' efforts to exclude this highly probative evidence must be denied.

7. Defendants' Omnibus MIL No. 7: The Court should exclude as irrelevant evidence that Defendants violated alleged duties under the CSA or its regulations.

In their Omnibus MIL No. 7, Defendants argue that evidence of their CSA violations is irrelevant because it does not establish certain elements of Plaintiffs' claims. First, that is not true, as discussed in greater detail below.[41] Moreover, Defendants are attempting to use this MIL to re-litigate issues decided on summary judgment, which the Sixth Circuit has held is improper. *See Louzon*, 718 F.3d at 558, 563 (defendant moved *in limine* to exclude plaintiff's "evidence of comparable employees on the basis that none were similarly situated as a matter of law[,]" arguing this evidence was irrelevant to plaintiff's discrimination claims; court held this was an improper motion *in limine*: "[T]his argument rests entirely on the presumption that Louzon would not be able to make out a prima facie case of discrimination, which if true would render null the need for any evidentiary rulings. Additionally, if these tactics were sufficient, a litigant could raise any matter in limine, as long as he included the duplicative argument that the evidence relating to the matter at issue is irrelevant. Where, as here, the motion in limine is no more than a rephrased summary-judgment motion, the motion should not be considered.").

This Court has determined that whether Defendants violated their duties under the CSA or its implementing regulations must be resolved by the jury in the upcoming trial:

[41] And, regardless, "a piece of evidence does not need to carry a party's evidentiary burden in order to be relevant; it simply has to advance the ball." *Dortch*, 588 F.3d at 401. *See also Morningstar*, 2018 WL 3721077, at *1 (same).

> The Court . . . finds the record is replete with disputes of material fact as to whether each Defendant complied with its obligations under the CSA, which preclude summary judgment. In these circumstances, it is a jury that must determine the credibility of the evidence, the weight to be given to the evidence, and any inferences to be drawn from the facts presented. Put simply, while the Defendants had a duty not to ship suspicious orders, there are disputes of fact as to whether, and when, each Defendant's SOMS was adequate, whether orders were suspicious, and whether each Defendant did actually ship suspicious orders (or instead, identified it as suspicious but then, through due diligence, dispelled that suspicion.

Dkt. #2483 at pp. 20-21 (internal citations omitted). *See also id.* at p. 32 ("[T]he Court finds the record is replete with material factual disputes regarding whether Defendants furnished false information or omitted material information, and, if so, whether they did so knowingly or intentionally."). By arguing that Plaintiffs cannot submit evidence of Defendants' CSA violations at trial, Defendants are effectively seeking to invalidate this Court's summary judgment rulings. This they cannot do.

Additionally, Defendants are simply wrong when they argue that their CSA violations are not relevant to Plaintiffs' claims. They largely reiterate the same erroneous arguments they made on summary judgment. These arguments were refuted in Plaintiffs' summary judgment briefing, which is incorporated by reference as if fully set forth herein. Dkt. #2545 at pp. 68-81; Dkt. #1924 at pp. 20-25. However, a number of their arguments bear some additional discussion here.

For example, Defendants claim that a violation of 21 U.S.C. § 843(a)(4)(A) "based on failure to comply with 'suspicious' order duties" cannot serve as a racketeering predicate act in this case. Dkt. #2661 at pp. 18-19. The Court has rejected this argument numerous times. Dkt. #2580 at p. 3 ("[T]he Court reaffirms its legal conclusion that a violation of 21 U.S.C. § 843(A)(4)(a) can constitute a predicate act under 18 U.S.C. § 1961(1)(D); and the Court further concludes that, at a minimum, Distributors have failed to demonstrate there is no genuine dispute of material fact regarding whether they violated § 842, § 843."); Dkt. #1025 at pp. 45-47; Dkt. 1203.[42]

[42] Additionally, Defendants' CSA violations are clearly felonious pursuant to § 841(a) and § 843(a)(4)(A). *See, e.g,* Dkt. #2545 at pp. 73-76.

Defendants also, yet again, argue that a violation of CSA *regulations* is not a violation of law punishable as a crime for purposes of 18 U.S.C. § 1961(1)(D).[43] But this Court has flatly rejected the argument that the relevant CSA regulations do not have force of law. Dkt. #2483 at p. 15 ("As a regulation promulgated pursuant to Congressional authority, Section 1301.74 is legislative in nature and has the full force and effect of law.") (citing cases). Defendants cite *U.S. v. Alghazouli*, 517 F.3d 1179 (9th Cir. 2008), in support of their argument, but that case is distinguishable. In *Alghazouli*, which did not involve RICO at all, the court decided whether a regulatory violation satisfied the "contrary to law" requirement in 18 U.S.C. § 545, a statute prohibiting the fraudulent or knowing importation of merchandise "contrary to law[.]" *Id.* at 1182-83. After analyzing the statutory history, the court determined "that Congress intended 'law', *as used in § 545*, to include a regulation only if a statute specifies that the violation of that regulation is a crime." *Id.* at 1187 (emphasis added). Unlike the statutes at issue in *Alghazouli*, CSA §§ 841 and 843 do not criminalize conduct that is "contrary to law," but rather conduct that violates "this subchapter" (*i.e.*, Subchapter I of the CSA and regulations promulgated thereunder).

Next, Defendants claim that evidence of their CSA violations "does not establish intent to defraud a victim of money or property, as required for mail and wire fraud[,]" citing *U.S. v. Daniel*, 329 F.3d 480, 485 (6th Cir. 2003). The cited portion of *Daniel* simply provides the elements of a wire fraud claim; that case does not involve or discuss violations of the CSA. 329 F.3d at 485. Defendants' CSA violations are certainly relevant to the issue of intent to defraud. Defendants intended to induce the medical community and individual patients to purchase more opioids than they otherwise would have purchased "by means of false or fraudulent pretenses, representations, or promises[.]" 18 U.S.C. § 1343; *Daniel*, 329 F.3d at 488 ("It is sufficient that the defendant by material misrepresentations intend the victim to accept a substantial risk that otherwise would not have been taken"). In order to serve that purpose, Defendants violated the CSA and made

[43] They further argue that because these violations are not relevant to establishing RICO predicates, they are not relevant to establishing "corrupt activities" for purposes of OCPA. Because the violations *are* relevant to establishing RICO predicates, Defendants' OCPA-related arguments also fail.

misrepresentations regarding same. Thus, evidence of Defendants' violations is relevant to Plaintiffs' wire and mail fraud allegations. Of course, even if Defendants' CSA violations were not relevant to their intent to defraud, they are relevant to various elements of Plaintiffs' other claims, as described herein.

Moving on to Plaintiffs' statutory public nuisance claim, Defendants reiterate their argument that CSA regulations do not constitute "laws . . . of the United States of America . . . controlling the distribution of a drug of abuse" for purposes of OHIO REV. CODE § 4729.35. Dkt. #2661 at p. 20. Again, this argument has already been rejected by this Court. *See* Dkt. #2483 at p. 15; Dkt. #2578 at p. 8 ("[T]he Court recently determined that the record demonstrates material issues of fact as to whether each Defendant complied with CSA obligations, and that conclusion applies here. Manufacturers' contention that no violation supporting the statutory nuisance claim has been identified in this litigation is without merit and does not warrant summary judgment.") (internal citation omitted). Defendants now try to argue that the fact that § 4729.35 separately lists "any rule of the board of pharmacy controlling the distribution of a drug of abuse" means that its reference to "laws" cannot be interpreted to include regulations. But "rules" are not the same thing as "regulations." Even the Controlled Substances Act differentiates between the two. *See, e.g.,* 21 U.S.C. § 821 ("The Attorney General is authorized to promulgate rules *and* regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances . . .") (emphasis added); 21 U.S.C. § 871(b) ("The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his function under this subchapter."). Under Defendants' interpretation, violating a "rule of the board of pharmacy controlling the distribution of a drug of abuse" is sufficiently "inimical, harmful, and adverse to the public welfare of the citizens of Ohio . . . to constitute a public nuisance[,]" but violating federal regulations controlling the distribution of a drug of abuse is not.[44] This makes no sense and is not consistent with the purpose of the statute, which is

[44] Presumably, if the Ohio legislature intended this interpretation, it could have easily used the word "statutes" instead of "laws."

to penalize "unlawful" distribution of "drug[s] of abuse," such as opioids. OHIO REV. CODE § 4729.35.

Sprietsma v. Mercury Marine, a Div. of Brunswick Corp., 537 U.S. 51 (2002), is inapposite. In that case, the Supreme Court was determining whether an express preemption clause in the Federal Boat Safety Act of 1971, which states that it applies to "a [state or local] law or regulation[,]" encompassed common-law claims. *Id.* at 63. The Court determined it did not, reasoning:

> [B]ecause "a word is known by the company it keeps," the terms "law" and "regulation" *used together* in the pre-emption clause indicate that Congress pre-empted only positive enactments. If "law" were read broadly so as to include the common law, it might also be interpreted to include regulations, which would render *the express reference to "regulation" in the pre-emption clause* superfluous.

Id. (internal citation omitted) (emphasis added).

Defendants next claim that their CSA violations are irrelevant to Plaintiffs' common law absolute public nuisance claims because Plaintiffs are required to prove that Defendants "violated a 'safety statute' " in order to recover on those claims. To begin with, that is not true. Defendants may also be held liable for intentional and unreasonable conduct causing the public nuisance. *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1143 n.4 (Ohio 2002) ("With an absolute nuisance, the wrongful act is either intentional *or* unlawful . . .") (emphasis added); CV 621.05 Absolute nuisance–intentional acts [Rev. 3-18-02], 1 CV Ohio Jury Instructions 621.05 ("Ohio has recognized that an intentional act can form the basis for an absolute nuisance.").[45] Moreover, the Ohio Supreme Court has clearly stated that violations of statutes *or regulations* involving public health or safety can establish a public nuisance: "[A] 'public nuisance' is 'an unreasonable interference with a right common to the general public.' 'Unreasonable interference' includes . . . conduct that is contrary to a statute, *ordinance or regulation* . . ." *Beretta*, 768 N.E.2d at 1142 (internal citations omitted) (emphasis added); *see also id.* (noting it has "often applied public nuisance laws to actions

[45] In *Taylor v. City of Cincinnati*, 55 N.E.2d 724 (Ohio 1944), the Ohio Supreme Court merely stated that the violation of a safety statute is one way to establish an absolute nuisance. *Id.* at 728. But the court also noted that an absolute nuisance can be established when "the actor commits and intentional act involving a culpable wrong." *Id.* at 727.

connected . . . to statutory *or regulatory* violations involving public health or safety") (emphasis added)).[46] Regardless, Plaintiffs have alleged violations of the CSA itself (*e.g.*, § 841, § 843) in Defendants' failure to maintain effective controls against diversion. The CSA is clearly a statute setting forth specific legal requirements for the protection of others. *See* 21 U.S.C. § 801 (in the introductory provisions to the CSA, Congress finds and declares that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people"). Finally, *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198 (Ohio 1998), is entirely inapposite as it addressed negligence *per se* claims, not nuisance claims. *Id.* at 200-03 (holding "the violation of an administrative rule does not constitute negligence *per se*").

Defendants' CSA violations also are relevant to Plaintiffs' civil conspiracy claims. In its order denying Defendants' summary judgment motion as to those claims, this Court explained that the "unlawful act" element of civil conspiracy "requires existence of an underlying unlawful act that is actionable in the absence of a conspiracy"[47] and that the unlawful act of any one member of the conspiracy is sufficient to satisfy this element. Dkt. #2562 at p. 4. The Court noted that Plaintiffs had alleged "unlawful acts of fraudulent marketing and Defendants' 'near uniform CSA noncompliance[,]' " and held that these issues "present[ed] factual disputes that must be evaluated by a jury." *Id.* Defendants' CSA violations are some of the unlawful activities on which Plaintiffs' underlying tort claims are based. Specifically, these violations form the basis of Plaintiffs' nuisance, RICO, and OPCA claims, all of which are torts separate from the conspiracy itself that Plaintiffs are pursuing against each Defendant. For that reason, Defendants' cases are inapposite.[48]

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46 *See also* RESTATEMENT (SECOND) OF TORTS § 821B(2)(b) (unreasonable interference with a public right may be shown by "conduct [that] is proscribed by a statute, ordinance, *or administrative regulation*") (emphasis added).

47 *See also* CV 443.01 Civil conspiracy [Rev. 12-1-07], 1 CV Ohio Jury Instructions 443.01 ("The unlawful act must be an unlawful act 'independent' of the existence of the conspiracy. In other words, there must be an underlying unlawful act actionable in the absence of the conspiracy.").

48 *See State ex rel. Morrison v. Wiener*, 83 N.E.3d 292, 295-99 (Ohio App. 9th Dist. 2017) (granting summary judgment on plaintiffs' civil conspiracy claim because plaintiffs failed to allege any underlying torts

As Defendants' CSA violations are relevant to all of Plaintiffs' claims, Defendants' request for an instruction to the jury as to the limited relevance of this evidence to particular causes of action should be denied. Dkt. #2661 at p. 22. Plaintiffs have no objection to the jury being instructed as to the definition of "suspicious orders" under CSA regulations. *Id.* However there is no basis, and Defendants fail to offer any justification, for "instructing the jury that 'suspicious' orders are not evidence of diversion or likely diversion." *Id.* The very purpose of monitoring for suspicious orders is to prevent diversion. Certainly evidence of an order that was, or should have been, flagged as suspicious is *some* evidence of likely diversion. If Defendants have proof that a particular suspicious order was not diverted, they are certainly able to make such an argument at trial. Defendants' requested instruction seeks to prevent the jury from weighing such evidence and is therefore improper and unwarranted.

Finally, Defendants ask the Court to preclude any testimony "that purports to set out, or opine on, the content of the law, whether on 'suspicious' order duties or any other subject." Dkt. #2661 at p. 22. Presumably, since Defendants request this relief, they will have no objection to Plaintiffs' *limine* request #13, which seeks to preclude "[a]ny argument or suggestion that the [CSA] and its implementing regulations do not impose, or have not always imposed, on registrants an identification duty, reporting duty, and no-shipping duty with respect to suspicious orders[,]" since such argument or suggestion would not only address the content of the law but directly contradict this Court's prior summary judgment rulings. Dkt. #2652 at pp. 10-11. Of course, Plaintiffs' *limine* request identified specific statements regarding the law that should be excluded because they would conflict with the Court's prior rulings. Defendants' request, on the other hand,

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supporting the conspiracy claim in their complaint and noting that even if the plaintiffs had pled the underlying torts they raised for the first time in their summary judgment response, they failed to meet their burden of pointing to any triable issues of material fact with respect to civil conspiracy based on those underlying torts); *Davis v. Clark Cty. Bd. of Commrs.*, 994 N.E.2d 905, 909-11 (Ohio App. 2d Dist. 2013) (dismissing plaintiff's civil conspiracy claim because the underlying torts on which he based that claim were barred by the statute of limitations); *Atanus v. S&C Elec. Co.*, 454 F. Supp. 2d 753, 756 (N.D. Ill. 2006) (noting that, in that case, the "success of [the plaintiff's tort] claims d[id] not depend upon a determination of whether defendants violated the regulation").

is overly broad, vague, and would encompass all legal conclusions (regardless of whether they conflicted with the law as determined by the Court). Dkt. #2661 at p. 22 ("The Court should therefore exclude any evidence on the meaning of law."). Whether certain testimony or evidence offers an inadmissible legal conclusion depends on the content of such testimony or evidence, and the context in which it is offered. As the Sixth Circuit noted in *U.S. v. Smith*, 70 Fed. Appx. 804 (6th Cir. 2003) (unpublished), when deciding whether testimony containing a legal conclusion should be allowed, " '[t]he best resolution . . . is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.' " *Id.* at 809 (citation omitted).[49] Thus, Defendants' blanket *limine* request should be denied.

8. <u>Defendants' Omnibus MIL No. 8</u>: The Court should require plaintiffs to establish the necessary foundation for their experts' testimony.

Defendants' request for a hearing prior to the presentation of any expert's testimony should be denied. While a party must establish the necessary foundation for their experts' testimony, pre-testimony hearings are neither required by the Federal Rules of Evidence nor necessary in this case, particularly given the significant resources this Court has already expended ruling on dozens of *Daubert* and summary judgment motions. *Cf.* FED. R. CIV. P. 1 (mandating that the parties and Court refrain from wasting resources).[50] Defendants' proposal would serve only to interrupt the trial and allow Defendants to re-litigate issues which they previously lost.

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[49] In that case, for example, the court held that a witness's opinion that the firearm at issue "belonged" to the defendant based on its location was admissible in an unlawful possession case. *Id.* ("Though Kurowski twice stated that he believed that the gun belonged to Smith, the term 'belong' does not have a meaning identical to the legal term 'possession' contained in the statute. Moreover, even if Kurowski had used the term "possession," in the present context, there is no distinction between the legal term of art and the common vernacular usage that would render the testimony inadmissible under [Federal] Rule [of Evidence] 704.").

[50] Plaintiffs proposed to stipulate to Defendants' language that: "The Parties shall be required to establish the necessary foundation for their experts' testimony." Defendants declined, instead indicating that for their motion to be mooted, an additional sentence would be required: "Before any expert is called to testify, the opposing side may request a hearing outside the presence of the jury to address whether the requirement has been satisfied." Such an additional mechanism not contemplated by the Federal Rules is not necessary to address Defendants' concerns in this case.

Defendants' cases do not support a different conclusion. Most instead emphasize that expert testimony is liberally admitted before a jury. *See McLean v. 988011 Ontario*, 224 F.3d 797, 806 (6th Cir. 2000) (reviewing a grant of summary judgment finding that the lower court had erred by prohibiting the expert testimony which was "sufficiently rooted in the available evidence to make out a reasonable theory . . . and [] plaintiffs should have been allowed to take their negligence theory to a jury"); *Andler v. Clear Channel Broadcasting, Inc.*, 670 F.3d 717, 729 (6th Cir. 2012) (applying the *Daubert* standards to the "district court's initial decision to exclude [Plaintiffs expert's] testimony was an abuse of discretion"); *Tovey v. Nike, Inc.*, 1:12CV446, 2014 WL 3510636, at *14 (N.D. Ohio 2014) (applying the *Daubert* standards to expert testimony). Given that this Court has already evaluated these experts' qualifications and opinions under the *Daubert* standard, there is no need to predetermine there is a need for a hearing in each case. To the extent such a need arises, if it arises, the Court is more than capable of making that determination during trial.

Another of Defendants' cases, *Shahid v. City of Detroit*, 889 F.2d 1543, 1547 (6th Cir. 1989), also supports permitting the court to make this determination at trial and discusses the proper method for objections to testimony based on assumptions not in evidence. The Sixth Circuit found that the district court did not err in excluding prior expert testimony via *videotape* "based on assumptions not in evidence, but rather assumptions based on plaintiff's version of events." *Id.* In doing so, the district court reasoned: "If you were asking these questions at this time there would be objections in terms of foundation or assumes a fact not in evidence, and I would have to sustain that objection, so we have a problem with this testimony." *Id.* Here, Plaintiff's experts will be testifying live and Defendants will have every opportunity to make such objections should Plaintiffs not lay the proper foundation for their expert's testimony.

Defendants also assert a variety of hypothetical arguments that Plaintiffs will ultimately be unable to demonstrate at trial that certain of their expert's assumptions are valid. Setting aside that Defendants are incorrect, what matters for present purposes is the point made above: Plaintiffs either will or will not lay a proper foundation for their experts, just as Defendants either will or will not lay a proper foundation for theirs. Additional hearings are wasteful. Indeed, the Court has

already ruled that any purported assumptions will be properly tested at trial, not that another *Daubert* hearing be held before the expert can testify. *See, e.g.*, Dkt. #2558 at p. 14 (Op. & Order Granting in Part and Denying in Part Mot. to Exclude Kessler and Perri) ("If this is a faulty assumption, as Defendants allege, they will have the opportunity for "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" to attack Perri's opinions." (citing *Burgett v. Troy–Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014)); Dkt. #2492, at p. 18 (Op. & Order Denying Mot. to Exclude Keller) ("If the party positing the hypothetical fails to independently prove the facts assumed, the jury is free to disregard the conclusion of the witness." (citing *United States v. McCafferty*, 801 F. Supp. 2d 605, 621 (N.D. Ohio 2011)); Dkt. #2495, at p. 13 (Op. & Order Denying Mot. to Exclude Rosenthal) ("Of course, Defendants are free to challenge Rosenthal's assumption – and Defendants may well convince a jury it is not true that all of defendants' detailing was fraudulent and tainted by misrepresentations – but her central assumption does not render her opinion inadmissible." (citing *Avery Dennison Corp. v. Four Pillars Enter. Co.*, 45 F. App'x 479, 487 (6th Cir. 2002)).

As noted, in the event Defendants later continue to disagree with a particular expert's testimony, they are able to address it by *inter alia* (i) cross-examination, (ii) their own case-in-chief, (iii) a Rule 50 motion, or (iv) another motion made at trial. The Court is perfectly capable of addressing any issues that may arise at trial without the need for further evidentiary hearings to ensure proper foundation. Defendants' Omnibus MIL No. 8 should be denied.

9. <u>Defendants' Omnibus MIL No. 9</u>: The Court should not allow use of certain charts presenting misleading and irrelevant data.

Defendants seek to exclude certain charts that are attached to Plaintiffs' expert Dr. Craig McCann's report[51] on the basis that they are potentially misleading. But Defendants identify nothing that is actually or inherently misleading about these charts. Each of the points raised by Defendants, that the charts include data relating to shipments outside the CT-1 jurisdictions and/or by non-

[51] Dkt. #2661 at p. 25 n. 19 (listing the charts Defendants seek to exclude).

defendants, and that charts do not identify specific pharmacies or specific diverted orders, is a matter that Defendants can readily address through objections to any direct examination of Dr. McCann that they believe is misleading and through their own cross-examination. Indeed, Defendants' challenges regarding the purported methodological flaws regarding Dr. McCann's processing of the ARCOS data and Defendants' own transactional data have already been rejected at the *Daubert* phase, with the Court specifically recognizing that Dr. McCann's methodological choices go to weight rather than admissibility, and permitting Defendants to cross-examine Dr. McCann on the choices he made. Dkt. #2494 at pp. 15-21.

The subject charts provide valuable background information in support of Dr. McCann's opinions, including information that Plaintiffs will use to show what orders – based on non-controversial data from ARCOS and Defendants' own production – should have been flagged as suspicious and therefore ultimately caused the harm Defendants are responsible for. Defendants' generalized concerns regarding how this data was analyzed or whether they are an appropriate methodological fit do not warrant their exclusion. *See, e.g., Goldman v. Healthcare Mgmt. Sys., Inc.*, 559 F. Supp. 2d 853, 871 (W.D. Mich. 2008) ("Factual questions should not be resolved through motions in limine."); *Cincinnati Ins. Co. v. Omega Flex, Inc.*, No. 3:10-CV-00670-H, 2013 WL 1403493, at *1 (W.D. Ky. Apr. 5, 2013) (denying motion *in limine* where cross examination would be sufficient to address deficiencies in expert testimony or opinions); *Quillen v. Safety-Kleen Sys., Inc.*, No. CIV.A. 07-67-EBA, 2010 WL 8357353, at *1 (E.D. Ky. May 27, 2010) (denying motion *in limine* where alleged errors in expert opinion could be the subject of cross examination).

10. <u>Defendants' Omnibus MIL No. 10</u>: The Court should prohibit counsel from offering personal opinions, using visual aids to belittle witnesses, and similar conduct.

As the Court has repeatedly noted, the parties in this litigation are represented by some of the most experienced and accomplished trial attorneys in the country. They all know how to try cases. Defendants' Omnibus MIL No. 10 is an attempt to improperly curtail proper, and long-standing, trial advocacy. Defendants' MIL seeks to preclude, among other things, "ad hoc drawings

or other visual aids during examination of witnesses," alleging that such tactics "belittle" witnesses or "mischaracterize" testimony. This assertion is wrong, and the MIL should be denied.

In the first place, the motion is overly broad and vague, making it practically unenforceable. *See In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prod. Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6740391, at *12 (S.D. Ill. Dec. 22, 2011) ("The Court finds that the request is too broad and will handle any individual objections at trial."). In *Yasmin*, the court denied two requested motions *in limine* because they were overly broad – one seeking to exclude "all evidence regarding unrelated corporate controversies," and one seeking to exclude "media reports." The court correctly concluded that those matters were better addressed during trial, when the relevance and admissibility of particular items could be more appropriately evaluated.

The same is true here. Lawyers have used visual aids in trial for decades – flip charts, white boards, and presumably chalk boards before those. The "ELMO" document projector is merely the latest iteration of the chalk board. There is nothing inappropriate or unusual about using such visual aids during witness examination. In fact, such aids are very useful in assisting the jury who are trying to follow complex testimony covering subject areas about which they likely have no prior experience. As one authoritative evidence treatise notes,

> It is today increasingly common to encounter the use of demonstrative aids throughout a trial. These aids are offered to illustrate or explain the testimony of witnesses, including experts, or to present a summary or chronology of complex or voluminous documents. Counsel also rely on such aids during opening and closing statements. Demonstrative aids take many forms; the types discussed in this Section are duplicates, models, hand drawn maps, charts, drawings, diagrams, and computer-generated pedagogic aids. *Unlike real evidence, the availability of which will frequently depend upon circumstances beyond counsel's control, opportunities for the use of demonstrative aids are limited only by counsel's ingenuity and ability to generate them. The potential of these aids for giving clarity and adding interest to spoken statements has brought about their widespread use, which will undoubtedly continue in the future.*

§ 214.Demonstrative aids, 2 MCCORMICK ON EVIDENCE § 214 (7th ed.). Defendants should be required to make specific and timely objections during trial, where the Court can rule on them in context rather than based on non-specific hypotheticals.

This MIL also attempts to impugn Mr. Lanier regarding evidence that a long-serving and well-regarded federal district judge determined was admissible to rebut misleading evidence adduced by the defendants in the trial. The court of appeals disagreed with the district court's evidentiary rulings, but that is no reflection on Mr. Lanier. The opinion omits the fact that the challenged evidence was only introduced after a series of lengthy sidebar discussions with the district court about whether the evidence should be admitted. As the court of appeals' opinion observes, "[t]he *district court* admitted several pieces of inflammatory character evidence against defendants—including claims of race discrimination and bribes to Saddam Hussein's Iraqi 'regime'—reasoning the defendants had 'opened the door' by repeatedly presenting themselves as 'wonderful people doing wonderful things.'" *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 764 (5th Cir. 2018) (emphasis added).

This portion of Defendants' Omnibus MIL is also too vague to be enforced. Every trial is unique. Even in the Pinnacle Hip Implant MDL, where the MDL court tried four lengthy bellwether trials (and started a fifth), each trial was different and the evidence that was admitted varied depending on the circumstances. Significantly, that court also explicitly recognized the high caliber of the plaintiffs' counsel's legal representation in that MDL. *See In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*, N.D. Tex., No. 3:11-md-02244-K, Dkt. No. 1031 (Order Granting Motion for Final Assessment, pp. 7-8) ("The skill requisite to perform the legal services properly was exceptional. Defendants were ably represented by multi-national law firms. At one point, Defendants asserted they had 50 lawyers working on this case. To fight Defendants to a draw—or, in reality, better—Plaintiffs' legal skill was readily apparent to even a casual observer."). Defendants' Omnibus MIL effectively could be read as requesting that Plaintiffs be precluded from doing anything at trial that could constitute reversible error. That is not the purpose of a motion *in limine*.

Next, the portion of this MIL regarding "references to unrelated bad acts" should be denied for the same reasons expressed by the court in *Yasmin*:

> Bayer asks that the Court prohibit any and all evidence regarding unrelated corporate controversies. Plaintiff counters, arguing that while most of the disputed controversies are likely irrelevant, the request is overbroad, vague, and not capable of enforcement.
>
> The Court could just as easily grant this motion because the request incorporates the language "unrelated." Thus, it would presume that the Court is only precluding that which is irrelevant. However, relevance is in the eye of the beholder. So while the Eli Lily example provided by the plaintiff in her response is in her view relevant, Bayer undoubtedly would disagree. The Court finds that the request is too broad and will handle any individual objections at trial.

Yasmin, 2011 WL 6740391, at *12.

With regard to "Golden Rule" arguments, Plaintiffs have no intention of making such arguments, and in fact agreed to a more specifically worded MIL proposed by Defendants that precludes "[a]ny reference to jurors' self-interest in the outcome of the litigation based on the jurors' status as taxpayers." *See infra* at § A.13.

In sum, Defendants' Omnibus MIL No. 10 should be denied because it is overly broad and vague, and the items which it seeks to exclude can only be properly considered in the context of the trial.

11. <u>Defendants' Omnibus MIL No. 11</u>: The Court should exclude evidence and argument concerning Defendants' financial condition, revenues, or profitability.

Defendants seek to exclude evidence about "defendants' overall financial condition, assets, revenues, or profitability." This motion is overbroad. Plaintiffs agree that they will not seek to introduce evidence of Defendants' overall financial condition or assets, as they are not seeking punitive damages, and neither RICO trebling nor OCPA trebling, which Plaintiffs do seek, depends on the defendant's ability to pay. But the request to exclude evidence of revenues and profitability stands on a different footing. Plaintiffs should be permitted to introduce and refer to evidence of the revenues and profits Defendants earned *from their opioid sales.* Evidence of profits earned from the conduct at issue is admissible to show the defendants' motive for engaging in that conduct. *See United States v. Amr*, 132 F. App'x 632, 635 (6th Cir. 2005); *Doe v. United States*, 253 F.3d 256, 269 (6th Cir. 2001). The evidence is probative of Defendants' willingness to engage in illegal conduct, and

thus of the likelihood that they did. Neither the jury nor the Court can properly assess whether, or understand how, Defendants could engage in the callous conduct at issue, involving indiscriminate dissemination of addictive drugs, without understanding the profits that were at stake. This evidence also shows the extent to which Defendants had the resources from their opioid business to design and maintain appropriate suspicious order monitoring and due diligence systems. It is thus probative of the extent to which their failure to do so was a deliberate choice, rather than reflecting, for example, a lack of resources. Because evidence of Defendants' opioid profits is highly relevant to both motive and intent, it should be not excluded.

12. Defendants' Omnibus MIL No. 12: The Court should preclude questioning of witnesses concerning their feelings and opinions of personal responsibility, guilt, or sympathy concerning the opioid crisis.

Defendants seek to preclude witness testimony concerning "personal feelings of personal responsibility or guilt relating to the opioid epidemic or their opinions about whether they or their employers violated legal requirements." Dkt. #2661 at p. 34. This request should be denied because it is vague, overbroad, and devoid of any specific context.

Defendants complain that "counsel for plaintiffs often asked" witnesses about their personal beliefs in depositions, yet fail to identify any examples of testimony they claim should be excluded. In the absence of specifically identified testimony, the Court cannot properly assess the potential relevance or prejudice of the evidence. *See Jackson v. O'Reilly Auto. Stores, Inc.*, 131 F. Supp. 3d 756, 760, 761 (M.D. Tenn. 2015) ("[W]e are unable to resolve Plaintiff's motion because he has not identified any particular piece of evidence that should be excluded. As a result, we cannot assess the likely relevancy or prejudice of the challenged evidence.").

Defendants' motion is also vague and overbroad. Terms such as "personal feelings" and "responsibility" could conceivably encompass a vast array of testimony, and Defendants' broad reference to those terms does little to provide the Court with any specific context upon which to base its rulings. *See Sperberg*, 519 F.2d at 712 ("Orders in limine which exclude broad categories of evidence should rarely be employed."). Without providing some minimal context for their motion

to exclude this broad category of testimony, Defendants are asking this Court to blindly exclude such evidence.

Further, the Court "has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds." *Indiana Ins.*, 326 F. Supp. 2d at 846. "Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Id.* Defendants cannot satisfy that standard here.

To the extent Plaintiffs can offer a response to Defendants' motion as it is presented, "testimony from individual witnesses affiliated with defendants" concerning their personal perception of their own or their employers' "responsibilities" is not inherently irrelevant or prejudicial. Such testimony would certainly be probative and relevant to central issues in this case, such as notice, standard of care, and causation. Defendants cite no case law supporting exclusion of the testimony under Rule 403, and they have not met their burden of demonstrating that the probative value of such testimony would be substantially outweighed by a risk of unfair prejudice.

Additionally, Defendants cannot show that such testimony is "clearly inadmissible" under Rule 701. *See Indiana Ins.*, 326 F. Supp. 2d at 846. Rule 701 permits lay witness testimony if it is rationally based on the witness's perception, helps the factfinder to understand the witness's testimony or to determine a fact in issue, and does not depend on scientific, technical, or other specialized knowledge within the scope of Rule 702. FED. R. EVID. 701. In applying Rule 701, "the modern trend among courts favors the admission of opinion testimony, provided that it is well founded on personal knowledge and susceptible to specific cross-examination." *United States v. Valdez-Reyes*, No. 03-3737, 2006 WL 126733, *4 (6th Cir. Jan. 18, 2006) (internal quotation marks and citation omitted). The Sixth Circuit has established that lay opinion testimony is proper where it is drawn from the witness's personal knowledge and experience gained through employment. *See U.S. v. Kerley*, 784 F.3d 327, 337-39 (6th Cir. 2015). Such testimony includes a witness's personal knowledge of his or her employer's policies and procedures, as well as the witness's experience in applying those procedures. *See id.* at 338.

Here, there can be no doubt that testimony regarding "personal feelings" is susceptible of firsthand knowledge. Witnesses affiliated with Defendants possess particularized knowledge about their own or their employers' policies and procedures by virtue of their employment. *See* FED. R. EVID. 701 adv. comm. note ("Such opinion testimony is admitted not because of experience, training or specialized knowledge within the realm of an expert, but because of the particularized knowledge that the witness has by virtue of his or her position in the business."). Because those procedures and policies are a central issue in this case, such testimony would facilitate understanding of a factual issue. Indeed, lay opinion testimony is particularly helpful "when the inference of knowledge is based on . . . such factors as the defendant's history or job experience." *United States v. Rea*, 958 F.2d 1206, 1216 (2d Cir. 1992). *See also, e.g.*, *United States v. Fowler*, 932 F.2d 306, 312 (4th Cir. 1991) (permitting Department of Defense officials to opine that a person with defendant's experience in the department would know rules forbidding giving certain documents to contractors); *United States v. Smith*, 550 F.2d 277, 281 (5th Cir. 1977) (allowing witness to testify to her belief that defendant who ran federally funded program understood certain federal regulations).

Finally, Defendants argue that such testimony impermissibly amounts to a legal conclusion and addresses an ultimate issue. Again, the absence of specifically identified testimony precludes a proper assessment of the testimony. Nevertheless, lay witnesses may testify as to their personal perception about certain responsibilities and procedures. Rather than constituting a legal conclusion, such testimony will provide factual information that will aid the factfinder in determining the ultimate legal issues in this case. Moreover, "[a]n opinion is not objectionable just because it embraces an ultimate issue." FED. R. EVID. 704.[52]

In sum, determinations regarding the admissibility of particular testimony are best left for trial, once such testimony has been identified and the purpose for which it is offered has been explained. If Defendants have an objection to specific deposition testimony that Plaintiffs have

[52] Defendants cite several cases for the general proposition that lay opinion on an ultimate issue must be helpful to the trier of fact. As explained above, the testimony Defendants challenge would facilitate understanding of a factual issue and is admissible under Rule 701.

designated for trial, it is appropriate for Defendants to object to that testimony in accordance with the Court's instructions. That would provide the appropriate context for the Court to make a specific evidentiary ruling.

13. Defendants' Omnibus MIL No. 13: The Court should bar Plaintiffs and their counsel from making statements at trial that appeal to the jurors in their capacity as taxpayers.

The parties conferred regarding this MIL and agreed to stipulate to a modified version. Specifically, both sides have agreed not to make "[a]ny reference to jurors' self-interest in the outcome of the litigation based on the jurors' status as taxpayers" in the presence of the jury.

14. Defendants' Omnibus MIL No. 14: The Court should preclude any comment regarding the absence of a corporate representative at trial.

Defendants' Omnibus MIL No. 14 should be denied because it is overbroad and premature. Whether or not a particular witness's absence is relevant depends on who the witness is and the relevant circumstances. This analysis should be deferred until trial so that questions of relevancy and potential prejudice may be resolved in proper context. For this reason, courts regularly deny similar motions *in limine*. *See Rembrandt Wireless Techs., LP v. Samsung Elecs. Co., Ltd.*, 2:13-CV-213-JRG-RSP, 2015 WL 627430, at *5 (E.D. Tex. Jan. 31, 2015) (denying defendant's motion to exclude reference to the absence of any its witnesses at trial); *Yasmin*, 2011 WL 6740391, at *11 ("The Court concludes, if no corporate representative is present at counsel table, said absence is fodder for comment by plaintiff since it is customary for such a person to be present. Certainly, if plaintiff was never present in the court room Bayer would feel compelled to comment. There are circumstances when a missing witness instruction is appropriate and that will not be precluded prior to trial.").[53]

[53] *See also Mitchell v. City of Tukwila*, C12-238RSL, 2013 WL 6631791, at *4 (W.D. Wash. Dec. 17, 2013) (denying plaintiff's motion *in limine* to preclude arguments "regarding the absence of specific witness testimony"; "[T]he parties will be allowed to present arguments regarding the absence of evidence. Whether the parties will be permitted to argue why certain witnesses have not testified cannot be determined in the absence of information regarding particular witnesses and the evidence presented at trial."); *Okuda v. Wyeth*, 1:04-CV-80 DN, 2012 WL 12337860, at *3 (D. Utah July 24, 2012) (denying defendants' motion *in limine* to preclude plaintiff "from making any reference to the absence of a corporate representative for [d]efendants at trial"; "The presence or absence of a corporate representative (or a fact witness) is not evidence but is a fact of the procedure of trial. It may

Significantly, not one of the cases cited by Defendants involved references to the absence of corporate representatives, or even motions *in limine*. *See U.S. v. Nixon*, 694 F.3d 623, 635-36 (6th Cir. 2012) (district court did not err in excluding the testimony of a witness in a criminal trial because that testimony was irrelevant); *U.S. v. Signer*, 482 F.2d 394, 398-400 (6th Cir. 1973) (in criminal trial for attempted income tax evasion and for making and signing false income tax returns, prosecutor's opening and closing arguments suggesting defendant committed a crime for which he was not on trial constituted reversible error); *U.S. v. Pits*, 85 F.3d 629, 1996 WL 254655, at *1 (6th Cir. 1996) (district court did not abuse its discretion in sustaining objections to statements made by defense counsel in his opening statement about the defendant regarding irrelevant matters, including that she is the mother of two small children, lived with her mother, had never before been arrested, and only recently learned the identity of her father); *U.S. v. Moore*, 651 F.3d 30, 51-55 (D.C. Cir. 2011) (addressing whether prosecutor committed prosecutorial misconduct during his opening and closing arguments in a criminal trial; although prosecutor crossed the line on several occasions, "the misconduct did not impermissibly and prejudicially interfere with the jury's ability to assess the evidence"), *aff'd in part sub nom. on other grounds*, *Smith v. U.S.*, 568 U.S. 106 (2013).

Because the factual circumstances of the absence of the specific witness should be considered, this category is not appropriate for a motion *in limine* and should be handled by individual objections during trial.[54] Defendants' Omnibus MIL No. 14 should be denied.

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be argued, and counter-argument may be made."); *Mascarenas v. Cooper Tire & Rubber Co.*, CV208-009, 2010 WL 11534359, at *10 (S.D. Ga. Jan. 11, 2010) (denying defendant's motion to exclude "any reference to the fact that it may not have a representative at trial at any particular time or to [the defendant's] choice of its corporate representative not being the appropriate person to respond to Plaintiffs' allegations").

[54] The risk of unfair prejudice is particularly low with respect to any such references made by Plaintiffs' counsel. What an attorney says is not evidence and the jury will be instructed accordingly. *Moore*, 651 F.3d at 54. If Defendants believe any additional instruction is necessary with respect to a particular reference made at trial, they should request it at that time, so the Court will have the full context necessary to decide their request.

B. PLAINTIFFS' RESPONSE TO OMNIBUS MEMORANDUM OF LAW IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE (DKT. #2666).

1. Distributors' MIL No. D-1: The Court should preclude Plaintiffs from offering evidence of, or arguments about, Distributors' settlements with the DEA and West Virginia.

Defendants have filed several motions *in limine* that seek to exclude evidence regarding their resolution of various enforcement actions taken by federal and state governments. The arguments asserted by Defendants in these MILs are very similar, so rather than repeat them in response to each MIL, Plaintiffs will address the legal standards and argument regarding these topics once, and will refer back to this argument on the specific points. If any specific additional information is necessary in response to a particular MIL, that will be addressed separately.

The argument and legal standards addressed here are applicable to the following MILs:

- Dkt. #2666 –Distributors' MIL No. D-1: Distributor settlements with the DEA and West Virginia.
- Dkt. #2645 – Henry Schein MIL Nos. HS-9 and HS-10: DEA fines, investigations, and Ohio Board of Pharmacy cease and desist letter (*infra* at § C.9-10).
- Dkt. #2648 – Walgreens' MIL No. W-2: DEA enforcement action and related settlement with Walgreens (*infra* at § D.2).
- Dkt. #2663-1 – McKesson MIL No. MCK-4: Allegations contained in letters from the DEA and DOJ to McKesson (*infra* at § F.4).
- Dkt. #2668-1 – Teva MIL No. TAD-1: Cephalon misdemeanor off-label promotion plea agreement (*infra* at § G.1).
- Dkt. #2668-1 – Teva MIL No. TAD-3: Cephalon settlement with DOJ (*infra* at § G.3).

The agreements are not precluded by Rule 408. Federal Rule of Evidence 408 generally prohibits the use of evidence of statements or conduct to compromise a claim "to prove or disprove the validity or amount of a disputed claim." However, "Rule 408 only bars the use of compromise evidence to prove the validity or invalidity of the claim that was the subject of the compromise, *not some other claim*." *Uforma/Shelby Bus. Forms, Inc. v. N.L.R.B.*, 111 F.3d 1284, 1293–94 (6th Cir. 1997) (citing Wright, et al., FEDERAL PRACTICE & PROCEDURE: EVIDENCE § 5314, 5308 (1st ed. 1980)

(internal citations omitted, emphasis added); *see also Gjokaj v. United States Steel Corp.*, 700 F. App'x 494, 501 (6th Cir. 2017). So Rule 408 does not even apply to the evidence Defendants seek to exclude, since that evidence does not involve the specific claims asserted by Cuyahoga and Summit Counties in this case.[55]

Moreover, even when Rule 408 applies, evidence of settlements *is* admissible where it is offered for "another purpose," such as "proving a witness's bias or prejudice, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution." FED. R. EVID. 408(b). The burden of establishing the application of Rule 408 is on the party invoking its protection. *William F. Shea, LLC v. Bonutti Research, Inc.*, No. 2:10-CV-615, 2012 WL 5077701, at *5 (S.D. Ohio Oct. 18, 2012).

Rule 408 is therefore "not a blanket rule that wholly precludes the consideration of settlement discussions." *Homoki v. Rivers Edge Tree Stands*, No. 1:12-CV-2926, 2012 WL 6631043, at *2 (N.D. Ohio Dec. 19, 2012). Instead, "evidence of such discussions may be admitted for any purpose not specifically excluded by the Rule." *Id.* As the rule makes clear, a settlement may be admissible where "it is offered for a purpose other than to prove liability or disprove a claim." *In re: E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, No. 2:13-CV-170, 2016 WL 659112, at *54 (S.D. Ohio Feb. 17, 2016). Accordingly, "the principal inquiry that determines whether Rule 408 bars introduction of evidence of [this evidence] must be toward the purpose for which the evidence is being offered." *McAuliffe v. United States*, 514 F. App'x 542, 549 (6th Cir. 2013).

The Sixth Circuit and Ohio district courts have recognized several purposes allowing for the admission of settlement evidence. One such purpose is establishing a party's knowledge or notice of potential harm. *See E.I Du Pont*, 2016 WL 659112, at *54 (consent decree was properly admitted when it was offered "as evidence of [Defendant] DuPont's knowledge and/or notice of C-8's

[55] This is also plain from the language of the rule, which repeatedly references "prov[ing] or disprov[ing] the validity or amount of **a** disputed claim" by offering evidence of conduct that occurred while attempting to resolve "**the** claim." *See* FED. R. EVID. 408(a)(1) and (2) (emphasis added).

potential for harm, not as evidence that DuPont acted negligently"). In this case, the multitude of enforcement actions and settlements establish a pattern of conduct demonstrating knowledge by Defendants that their SOM systems were inadequate and were likely to cause harm – not just in the specific locations where the enforcement actions focused, but throughout the country. That is particularly true in this case, where Defendants have claimed that they lacked understanding of their legal duties.

Another permissible purpose is to prove a party's state of mind. *See Croskey v. BMW of North America, Inc.*, 532 F.3d 511, 519 (6th Cir. 2008) ("settlement evidence was not offered as a defense to plaintiff's negligence claims against BMW, but instead was offered to show the state of mind of the witnesses"); *McAuliffe*, 514 F. App'x at 549-50 ("It is plain from the record that the contents of the conversation were not offered in McAuliffe's criminal trial to prove the liability of either one in the civil dispute or the amount of those claims. Instead, the evidence was offered for the other purpose of showing McAuliffe's knowledge of and participation in illegal acts—in other words, his state of mind, which Rule 408 allows.").

With regard to Plaintiffs' nuisance claims, the Court identified as disputed issues of fact for trial in its rulings on the parties' motions for summary judgment: (1) whether a public nuisance exists (Dkt. #2572 at p. 4); (2) whether the opioid epidemic interferes with public health and public safety rights (Dkt. #2578 at p. 4); (3) whether Defendants' conduct substantially contributed to Plaintiffs' injuries (*id.* at p. 5); and (4) whether Defendants' conduct was intentional or unlawful (*id.* at pp. 5-7). The enforcement actions demonstrate that Defendants' conduct was intentional and persisted over a lengthy period of time, which goes to the heart of Plaintiffs' claims.

The agreements are admissible under Rule 406. Evidence of "an organization's routine practice . . . to prove that on a particular occasion the . . . organization acted in accordance with the . . . routine practice" is admissible. FED. R. EVID. 406; *CSX Transp., Inc. v. Exxon/Mobil Oil Corp.*, 401 F. Supp. 2d 813, 818 (N.D. Ohio 2005) (finding the evidence of performing inspections and "observations made during the inspections, [are] admissible under Fed. R. Evid. 406 as proof of habit or routine practice"). "Rule 406 evidence must rest on an analysis of instances numerous

enough to support an inference of systematic conduct and to establish one's regular response to a repeated specific situation." *Bell v. Consol. Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio 2004) (internal citations and quotations omitted). Courts may consider three elements to determine whether the organization's routine practice is admissible under Rule 406: (1) whether "it is unlikely that the individual instance can be recalled or the person who performed it can be located," (2) whether the "specific conduct … is engaged in frequently by the group," and (3) whether "the number of instances of such behavior [is] large enough that doubt about a single instance does not destroy the inference that the practice existed." *Martin v. Thrifty Rent A Car*, 145 F.3d 1332 (6th Cir. 1998).

Defendants' conduct that forms the bases of the DEA/DOJ agreements occurred "with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances." *Bell*, 299 F. Supp. 2d at 800. The agreements and related documents establish that Defendants engaged in "systematic, particularized, and repetitive conduct" by selling prescription opioids without proper, effective controls to prevent diversion and to identify, report, and stop shipment of suspicious orders. As the agreements describe, the temporal and geographic scope of this systematic conduct (covering millions of transactions) was so extensive that it cannot be evaluated by a singular instance, nor can a single instance destroy the inference that this was a routine practice.

Both Cardinal Health and McKesson agreed to pay significant fines in 2008 relating to their failure to comply with their obligations under the Controlled Substances Act. Despite agreeing to comply with those obligations, both companies continued to ignore them and were the subject of later enforcement actions by the federal government roughly a decade later, reflecting their persistent failure to conform their conduct to the law. In connection with those later enforcement actions, Cardinal and McKesson acknowledged that they had not lived up to their prior agreements. This history of repeated violations of their legal duties shows that Defendants' violations were not the result of mere oversight, but reflected Defendants' intentional and ongoing business practices.

As a result, the agreements are admissible under Rule 406 because they prove Defendants acted in accordance with their routine practice.

The agreements are relevant. Evidence is relevant where it "has any tendency to make a fact more or less probable than it would be without the evidence," and "the fact is of consequence in determining the action." FED. R. EVID. 401. Generally, "[r]elevant evidence is admissible" while "[i]rrelevant evidence is not admissible." FED. R. EVID. 402.

Defendants' meritless relevance arguments are wholly divorced from an analysis of the substantive law governing the claims and defenses at issue. The DEA/DOJ agreements are relevant evidence for several claims at issue. For instance, as part of Plaintiffs' RICO and Ohio Corrupt Practices Act (OCPA) claims against McKesson, Cardinal, and AmerisourceBergen, Plaintiffs seek to establish that these Defendants formed and operated an opioid supply chain to expand their sales of prescription opioids through repeated violations of the CSA. Defendants failed to maintain effective controls to prevent diversion and filled suspicious orders for opioids. The DEA/DOJ agreements describe investigations and findings by the DEA and the DOJ concerning the same violations alleged here. The agreements also describe the multiple suspension orders and ISOs which provided notice to Defendants that their suspicious order systems were ineffective and were being abused.

Evidence regarding Defendants' repeated violations of their duties under the CSA demonstrates that Defendants continued the conduct in the face of confirmed proof that such conduct was contributing to the opioid epidemic. These agreements are therefore relevant to establish Defendants' RICO and OCPA violations.

Distributor Defendants argue that the settlement agreements are not relevant because some of them "disclaim any admission or concession of liability," and even those that contain "narrow admissions" do not implicate the distribution of opioids into Summit and Cuyahoga Counties. Dkt. # 2666 at p. 5. Defendants therefore attempt to cabin the relevance of the agreements to the distribution centers at issue there. Yet, the agreements make it clear that they apply to all (or at least most) distribution centers. The McKesson 2017 Agreement, for example, expressly states that

"[t]his Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances." Dkt. #2212-29; Dkt. #2557-3. AmerisourceBergen's obligations are similarly not limited to any particular Distribution Centers.

These arguments also fail to acknowledge that the conduct about which Plaintiffs complain is not limited to conduct that occurred in Cuyahoga and Summit Counties. Instead, Plaintiffs' allege that the harm they suffered was caused by conduct that occurred all across the nation, over many years, which was a substantial factor in causing the nuisance condition that persists in those counties and also gives rise to Plaintiffs' other claims. This issue is discussed more fully in response to Walgreens' MIL No. W-2, *infra* at § D.2, regarding a 2007 DEA enforcement action in Florida, which explains how Defendants' failures to adequately monitor sales to prevent diversion in one geographic location affects other locations, including the Plaintiff counties.

The agreements are not unfairly prejudicial. Although relevant evidence is generally admissible, "Rule 403 carves out a narrow exception to this broad rule of admissibility." *United States v. Schrock*, 855 F.2d 327, 333 (6th Cir. 1988). Relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." *Id.*; FED. R. EVID. 403. As the permissive language of the rule makes clear, a court may admit evidence even where there is potential prejudice, and "[this] decision to admit relevant, but potentially prejudicial, evidence is committed to the sound discretion of the trial court." *Id.* "When the district court admits evidence over a party's undue-prejudice objection, [the 6th Circuit] review[s] the admitted evidence in the light most favorable to its proponent, maximizing its probative value and minimizing its prejudicial effect." *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018) (citation omitted).

Here, any danger of unfair prejudice or confusion is quite limited because the practices described in the DEA/DOJ agreements pertain directly to Defendants' controls to prevent diversion and the filling of suspicious orders for opioids. Thus, this evidence will not confuse the

issue nor inject extraneous factual matters into the trial. Nor would a jury be likely to take this evidence as a concession of liability – although the evidence is factually on point, the *legal* context of the agreements is so distinct that a jury is not likely to believe that an agreement with the government to settle what are in effect charges for CSA violations amount to an admission of liability to the alleged RICO, OCPA, and public nuisance claims. And, to the extent that the jury credits the factual statements in the agreements, this does not constitute "unfair" prejudice. Even if that were the case, the Court can ensure, through trial rulings and jury instructions, that the context in which the facts were developed does not overwhelm the import of the evidence itself.

For these reasons, Distributor Defendants' arguments that their distributor settlements with the DEA and West Virginia are irrelevant, prejudicial, or inadmissible under Rule 408, are without merit. Distributor Defendants' MIL No. D-1 should be denied.

2. Distributors' MIL No. D-2: The Court should preclude non-party corporate representatives from testifying to matters outside their personal knowledge.

Distributor Defendants broadly seek to preclude the admission of non-party 30(b)(6) witness testimony "on matters outside the witness' personal knowledge," arguing such evidence is inadmissible hearsay and lacks foundation. For the following reasons, Distributor Defendants' MIL No. D-2 should be denied.

Contrary to Distributor Defendants' assertion, Rule 602's personal knowledge requirement does not preclude the introduction of 30(b)(6) testimony at trial that is beyond the witness' direct personal knowledge. It is well established that a corporate designee testifying pursuant to Rule 30(b)(6) "does not testify as to his personal knowledge or perceptions [but rather] testifies 'vicariously,' for the corporation, as to its knowledge and perceptions." *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 434 (5th Cir. 2006). *See also Lloyd v. Midland Funding, LLC*, No. 15-5132, 639 Fed. Appx. 301, 305 (6th Cir. Jan. 22, 2016) (citing *Brazos*). As such, Rule 30(b)(6) provides a recognized exception to the personal knowledge requirement set forth in Rule 602.

Although Rule 30(b)(6) refers by its terms to depositions, courts have recognized that a 30(b)(6) witness may testify at trial despite a lack of personal knowledge about the matters described.

See Brazos, 469 F.3d at 434 (permitting 30(b)(6) trial testimony concerning "the collective knowledge or subjective belief of [the corporation] . . . even if it is not within his direct personal knowledge"); *Univ. Healthsystem Consortium v. UnitedHealth Grp., Inc.*, 68 F. Supp. 3d 917, 921 (N.D. Ill. 2014) ("[A] Rule 30(b)(6) witness may testify both in a deposition and at trial to matters as to which she lacks personal knowledge, notwithstanding the requirements of Federal Rule of Evidence 602."). Relatedly, numerous courts, including the Sixth Circuit, have permitted 30(b)(6) witness testimony addressing corporate matters outside of the witness' personal knowledge in summary judgment proceedings. *See, e.g.*, *Lloyd*, 639 F. App'x at 305 (finding corporate representative's testimony based on his review of corporate records satisfied personal knowledge requirement under Federal Rule of Civil Procedure 56); *PPM Finance, Inc. v. Norandal USA, Inc.*, 392 F.3d 889, 894 (7th Cir. 2004) (holding non-party 30(b)(6) witness "was free to testify to matters outside his personal knowledge as long as they were within the corporate rubric").

With respect to *non-party* 30(b)(6) witness testimony, the court in *Sara Lee Corp. v. Kraft Foods, Inc.*, 276 F.R.D. 500 (N.D. Ill. 2011) specifically rejected the argument that a non-party 30(b)(6) witness could not testify at trial regarding matters outside his or her personal knowledge. *See id.* at 503 ("This Court . . . will not limit . . . testimony strictly to matters within [his] personal knowledge"). The court reasoned that to rule otherwise "would only recreate the problems that Rule 30(b)(6) was created to solve." *Id.* "For example, a party might force a corporation to 'take a position' on multiple issues through a Rule 30(b)(6) deposition, only to be left with the daunting task of identifying which individual employees and former employees will have to be called at trial to establish the same facts." *Id.* The court concluded that proper areas of testimony for non-party Rule 30(b)(6) witnesses include "topics . . . about which the corporation's official position is relevant . . . ." *Id.* at 503.

Second, 30(b)(6) testimony that is beyond personal knowledge is not inherently inadmissible hearsay. *See, e.g.*, *Pugh v. City of Attica, Ind.*, 259 F.3d 619, 627 n.7 (7th Cir. 2001) (finding, in the summary judgment context, that City Attorney O'Conner's "answers to the interrogatories were not hearsay because the City had designated O'Connor to testify to matters known or reasonably

available to the City."). While the *Sara Lee* court acknowledged the risks of admitting non-party 30(b)(6) testimony based on hearsay, it reasoned that limiting such testimony to matters "particularly suitable for Rule 30(b)(6) testimony" sufficiently mitigated the risk. 276 F.R.D. at 503.

Here, Distributor Defendants' motion is overbroad and completely devoid of context. They seek a blanket evidentiary ruling based on hearsay and lack of foundation and mistakenly assume that if Plaintiffs offer non-party 30(b)(6) testimony beyond a witness' direct personal knowledge, then such evidence must be offered for the truth of the matter. Determinations regarding the admissibility of a particular third-party statement are best left for trial, once such statement has been identified and the purpose for which it is offered has been explained. *See Chimney Rock Pub. Power Dist. v. Tri-State Generation & Transmission Ass'n, Inc.*, No. 10-CV-02349-WJM-KMT, 2014 WL 1583993, at *3 (D. Colo. Apr. 21, 2014) ("Defendant's Motion identifies no specific evidence it seeks to exclude from Plaintiffs' Rule 30(b)(6) designees. Instead, Defendant makes general reference to evidence that may be inadmissible hearsay, and asks the Court to restrict the testimony of Plaintiffs' witnesses without any indication of what such evidence will show, or for what purpose it will be offered. The Court will not issue such a blanket evidentiary ruling, particularly where a fact-intensive evaluation of hearsay exceptions may be necessary.") (internal citation omitted).

Distributor Defendants offer two examples of testimony they claim should be excluded from the 30(b)(6) deposition of DEA employee, Thomas Prevoznik, in which he identified a DEA report and DEA presentation.[56] However, such testimony addresses "matters about which the corporation's official position is relevant" and therefore falls squarely within the realm of permissible trial testimony for non-party 30(b)(6) witnesses. *See Sara Lee*, 276 F.R.D. at 503.

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[56] These DEA documents could be admitted for a number of non-hearsay reasons, such as to prove (i) that the statement was made, (ii) the falsity of the matter asserted, (iii) the knowledge of the declarant, (iv) notice to, or knowledge of, the recipient of the statement, (v) motive, intent, bias, or state of mind, or (vi) association among persons or entities. And *if* Plaintiffs offered the evidence for the truth of the matter, the documents could fall within a hearsay exception in Rule 803, such as: a record of regularly conducted activity under Rule 803(6); a public record or report under Rule 803(8); or, a statement in an ancient document under Rule 803(16).

Further, the official DEA report and presentation Mr. Prevoznik identified sharply contrast with the type of evidence excluded in the cases Distributor Defendants cite. For instance, in *Cooley v. Lincoln Elec. Co.*, 693 F.Supp.2d 767, 791 (N.D. Ohio 2010), the defendant's 30(b)(6) witness sought to explain the company's position at trial using a recent conversation he had with the CEO. The court barred the proposed explanatory testimony on the basis of hearsay. *Id.* at 791-92. Significantly, the hearsay at issue in *Cooley* was of questionable reliability. Stephen J. O'Neil, *Rule 30(b)(6) Witnesses at Trial*, 60 Fed. Law. 70, 73 (September 2013) ("[T]he result in *Cooley* might be different if the Rule 30(b)(6) witness had learned of additional information in the discovery record as opposed to the undiscoverable water-cooler conversation with the CEO, or if the Rule 30(b)(6) witness had learned of new information at trial that was not in the discovery record but was verifiable and reliable."). Similarly, the testimony found to be improper in *Union Pump Co. v. Centrifugal Tech. Inc.*, Nos. 10–30040, 10–30072, 2010 WL 5186616, at *6-7 (5th Cir. Dec. 16, 2010) involved facts the 30(b)(6) witness learned "solely through conversations with others" and of which there were no written reports. *Cf. Sara Lee*, 276 F.R.D. at 503-04 (considering "whether the underlying corporate knowledge is *sufficiently reliable* to substitute for personal knowledge") (emphasis added).

For all these reasons, the Court should deny Distributor Defendants' MIL No. D-2 in its entirety and defer ruling on issues regarding the foundation for admitting Mr. Prevoznik's and other 30(b)(6) witness' testimony until trial.

3. <u>Distributors' MIL No. D-3</u>: The Court should exclude any evidence of criminal indictments and investigations without corresponding proof of a final judgment of conviction.

In March of 2019, David Gustin, the former compliance officer for McKesson's warehouse in southern central Ohio, was indicted on one count of conspiracy for allegedly violating the Controlled Substances Act.[57] Mr. Gustin's lawyer described the charge as follows: "The United

[57] *See* "Feds probe manager of McKesson narcotics distribution warehouse in Ohio," *The Washington Post*, Sept. 18, 2019, available at https://www.washingtonpost.com/health/feds-probe-manager-of-mckesson-narcotics-distribution-warehouse-in-ohio/2019/09/18/0878fd26-d644-11e9-9610-

States' theory seems to be that Mr. Gustin was so woefully negligent in overseeing his compliance responsibilities that his conduct was criminal." The article reports that McKesson has received subpoenas from the federal government and is cooperating with the government's investigation, and that "documents [filed in the criminal case] also show that Gustin and McKesson have an agreement to work together on the legal case." So McKesson is obviously fully aware of the circumstances and conduct giving rise to Mr. Gustin's indictment.

Although the indictment and related documents are included on Plaintiffs' exhibit list, Plaintiffs do not intend to introduce these documents unless necessary for some other purpose, such as impeachment. However, Plaintiffs are not precluded from inquiring about the *conduct* at issue in the indictments. Whether the former director of regulatory affairs for McKesson's warehouse in Ohio engaged in conduct that violated the Controlled Substances Act involving the distribution of prescription opiates is certainly relevant to Plaintiffs' claims.

4. Distributors' MIL No. D-4: The Court should prohibit Plaintiffs from stating expressly or suggesting that the jury may infer that an older document never existed just because it cannot be found.

Distributor Defendants' MIL No. D-4 seeks to preclude Plaintiffs, or any of their experts, from "suggesting" that the "fact that suspicious order reports and due diligence files from five, ten, or twenty years ago cannot be located today does not mean they never existed." Dkt. #2666 at p. 13. Their purported basis is that there is no "requirement to maintain such records for any period of time," and Plaintiffs have failed to satisfy the Sixth Circuit's adverse inference test. *Id.*

This argument is virtually identical to the argument Defendants raised in their *Daubert* motion against Mr. Rafalski, which has already been rejected by this Court:

> Defendants reply that, if the law does not require them to maintain due diligence records, Rafalski has no basis to conclude they did not conduct due diligence based on the absence of those records. Based on his experience as a DEA Diversion Investigator, however, Rafalski may opine as to what the absence of due diligence records indicates to him. *Moreover, it is notable that Defendants do not contradict Rafalski by explaining they did conduct due diligence but don't have any documents to support it.*

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fb56c5522e1c_story.html (accessed on 10/6/19).

Dkt. #2494 (Opinion and Order Regarding Defendants' Motion to Exclude Opinions of James Rafalski and Craig McCann) at p. 13 (emphasis added).

Moreover, in bringing this motion, Distributor Defendants once again incorrectly argue that the absence of documents is the "sole" basis for Mr. Rafalski's conclusion that they failed to perform due diligence. But as pointed out in Plaintiffs' *Daubert* opposition brief (Dkt. #2253 at pp. 13-14), the bases for Mr. Rafalski's conclusions are his detailed review of Defendants' SOM program, Defendants identification of an absurdly trivial number of suspicious orders, and policies and practices that allowed certain Defendants to ship orders before any due diligence could be carried out. In light of this evidence, it falls to Defendants to establish that their purported due diligence nonetheless took place. As Mr. Rafalski found, Defendants' files are devoid of any such evidence, and as the Court itself emphasized, "it is notable that Defendants do not contradict Rafalski by explaining they did conduct due diligence but don't have any documents to support it." Dkt. #2494 at p. 13.

Distributor Defendants' reliance on the Sixth Circuit's adverse inference test is also inapposite. There is a difference between asking the fact-finder to draw inferences adverse to a party from the evidence presented (which presumably both parties intend to do at trial) and asking the Court to issue an adverse inference instruction. Distributor Defendants' test applies in the latter case, and at this time, Plaintiffs are not seeking such an instruction. In fact, Plaintiffs are not arguing that documents were necessarily destroyed, as opposed to never existing in the first place because Defendants failed to perform any due diligence. One can infer from the absence of due diligence materials that no due diligence was performed, or that if due diligence was performed, but not documented, this is an indication of an inadequate due diligence program. There is nothing improper about Plaintiffs, or their experts, advocating for such an inference. In rejecting Defendants' *Daubert* argument, the Court has already ruled that Mr. Rafalski can offer this as an expert opinion:

> As a former Diversion Investigator, Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an

> effective SOMS and due diligence program. Indeed, Defendants do not challenge his credentials in this regard . . .
>
> Defendants ask the Court to preclude Rafalski from stating that the law requires registrants to document and retain forever suspicious order reports and due diligence records. It is Rafalski's position that, while the regulations do not require a registrant to retain these documents for any specific length of time, in his opinion, permanent retention is important to maintaining effective control and preventing diversion. See Rafalski Depo. at 125:11 to 126:3. *For the reasons stated above, Rafalski may opine as to the need for documentation to maintain effective control; however he may not state what the law requires in this regard.*

Dkt. #2494 at pp. 8, 10 (emphasis added).

For these reasons, Distributor Defendants' MIL No. D-4 should be denied.

5. <u>Distributors' MIL No. D-5</u>: The Court should prohibit Plaintiffs from presenting evidence or making arguments suggesting Distributors committed a "fraud on the DEA."

Through their MIL No. D-5, Distributor Defendants attempt to re-litigate their preemption argument in the guise of a motion *in limine*. Indeed, the vast majority of their argument is that Plaintiffs' due-diligence based claims are preempted under *Buckman Co. v. Plaintiffs' Leg. Comm.*, 531 U.S. 341 (2001). But as this Court has held several times, Plaintiffs are not asserting claims for fraud on the DEA (or FDA), and thus, their claims are not preempted under *Buckman*. Dkt. #2565 at pp. 9-10, 22; Dkt. #1025 at pp. 50-51; Dkt. #1203 at p. 2.

However, this does not render evidence regarding their interactions with the DEA irrelevant or inadmissible.[58] To the contrary, this evidence is highly relevant to a wide range of issues, including Defendants' knowledge, motive, intent, and state of mind, as well as their violations of the CSA, fraudulent misstatements to the public and the medical community, and their conspiratorial conduct and objectives. *See, e.g., Mahaney ex rel. estate of Kyle v. Novartis Pharm. Corp.*, 835 F. Supp. 2d 299, 318 (W.D. Ky. 2011) ("[T]he fact that Plaintiff intends to introduce evidence that NPC violated FDA regulations does not automatically implicate the holdings of *Buckman* and *Kemp*. State-law

[58] *See Tylenol*, 181 F. Supp. 3d at 289 n.9 (noting that "whether the evidence related to the defendants' interactions with the FDA is admissible for purposes other than establishing liability or breach of duty" is "a different inquiry than whether the plaintiff's claims are preempted").

causes of action that track federal regulatory regimes have not been preempted by these decisions . . . . Evidence of violations of the FDA's regulations that are introduced to support the state-law torts is admissible."), *order vacated in part on other grounds on reconsideration sub nom. Mahaney on behalf of estate of Kyle v. Novartis Pharm. Corp.*, 1:06-CV-00035-R, 2012 WL 12996015 (W.D. Ky. Jan. 4, 2012); *Tylenol*, 181 F. Supp. 3d at 289–90 (denying defendants' motion *in limine* to exclude evidence or argument relating to fraud on the FDA because "evidence that the defendants attempted to manipulate the regulatory process, failed to comply with regulatory duties, or adhere to guidance provided by the FDA can be used to show other elements of the plaintiff's claims[,]" including "the defendants' state of mind, motive, or knowledge of a defect"; "It also would be relevant to the plaintiff's fraud claims if the information the defendants sent to or received from the FDA was different from what the defendants were communicating to consumers[.]").[59] Moreover, as Defendants have indicated that they intend to argue that the DEA failed to vigorously enforce the law, their misstatements regarding their SOMS programs, reporting of suspicious orders, and efforts to prevent diversion are directly relevant to facts that Defendants themselves are putting at issue.

Distributor Defendants' sole argument against the admissibility of this evidence is their conclusory statement, citing nothing but Rule 402 and 403, that "testimony, evidence, or argument that Distributor Defendants have misled the DEA by failing to report suspicious orders, or

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[59] *See also Yasmin*, 2011 WL 6740391, at *2 (denying similar motion *in limine* implicating fraud-on-the-FDA; "In a case such as this, the jury must be fully informed of any information withheld from the FDA that could have effected decisions regarding the label."); *Adams*, 2009 WL 1259019, at *1 ("The Court has ruled in a prior decision . . . that evidence of communications between DuPont and the agencies is not excludable simply because the Court dismissed the fraud-on-the-agency claim. The evidence of such communications is relevant for other purposes, such as proving the claims of misbranding or failure to warn."); *In re Vioxx Products Liab. Litig.*, MDL 1657, 2005 WL 3164254, at *1 (E.D. La. Nov. 21, 2005) (denying defendant's motion *in limine* to exclude evidence or argument preempted by federal regulations, including that the defendant "committed 'fraud' on the FDA, misled the FDA, did not cooperate with the FDA, or otherwise violated the Food, Drug, and Cosmetic Act and its implementing regulations[,]" noting that "[t]his is an issue of proof and will have to be dealt with at time of trial"); *Globetti v. Sandoz Pharm. Corp.*, CV98-TMP-2649-S, 2001 WL 419160, at *3 (N.D. Ala. Mar. 5, 2001) (denying defendant's motion *in limine* based on *Buckman*; "While plaintiff may not offer evidence simply to show misrepresentations to or concealment from the FDA, such evidence may be relevant to showing the defendant's knowledge relating to the adequacy of the warning or the truth of information represented to or concealed from plaintiff or her physician.").

otherwise failing to submit the required information" is "irrelevant, prejudicial, and would risk confusing the jury." Dkt. #2666 at p. 15. This does not come close to satisfying their high burden of demonstrating such evidence is clearly inadmissible on all potential grounds. *Supra* at pp. 2-3. Distributor Defendants' MIL No. D-5 should be denied.

6. Distributors' MIL No. D-6: The Court should prohibit counsel and witnesses from making references broadly and generally to "Defendants" when the statement, argument, or testimony relates only to certain specific Defendants or groups of Defendants.

Distributor Defendants seek to prohibit Plaintiffs' counsel and witnesses from referring to "defendants" generally at trial, contending it will violate Federal Rule of Evidence 403. Federal Rule of Evidence 403 authorizes the exclusion of relevant evidence if its probative value is *substantially outweighed* by the danger of unfair prejudice, confusion of the issues, or misleading the jury. FED. R. EVID. 403. "Exclusion under Rule 403 is an extraordinary measure that should be exercised sparingly." *Antioch Co. Litig. Tr. v. Morgan*, No. 3:10CV156, 2014 WL 2117450, at *1 (S.D. Ohio May 21, 2014) (citing *United States v. Morris*, 79 F.3d 409, 412 (5th Cir. 1996)).

None of the cases Defendants cite demonstrate that categorical references to defendants are improper in the context of a motion *in limine* or under Rule 403. Instead, they discuss concerns related to "lumping" defendants in a jury charge or complaint.[60] Of course, those concerns are not implicated at this stage of the litigation, and Plaintiffs have no intention of "lumping" Defendants together in the jury charge.

Distributor Defendants' motion is also overbroad and highly impractical, and its enforcement would unduly police the speech of Plaintiffs' counsel and witnesses at trial. Requiring

[60] *See Marcilis v. Twp. of Redford*, 693 F.3d 589, 596 (6th Cir. 2012) (noting damage claims against government officials arising from constitutional rights violations must allege particular facts against each defendant); *Rui He v. Rom*, No. 1:15-CV-1869, 2017 WL 1054814, at *4-5 (N.D. Ohio Mar. 21, 2017) (finding lumping of defendants on jury form was proper); *Christopher Seri v. Crosscountry Mortg., Inc.*, No. 1:16-CV-01214-DAP, 2016 WL 5405257, at *4 (N.D. Ohio Sept. 28, 2016) (dismissing complaint); *Reo v. Caribbean Cruise Line, Inc.*, No. 1:14 CV 1374, 2016 WL 1109042, at *1 (N.D. Ohio Mar. 18, 2016) (holding that lumping defendants in complaint did not require dismissal).

Plaintiffs' counsel to approach the bench before using the word "defendants" would inevitably impede the flow of trial and interfere with the presentation of evidence. And given the breadth of the restriction, it would necessitate numerous side bars addressing whether various statements, arguments, or testimony relate to certain Defendants. Plaintiffs' counsel and witnesses should be permitted in their discretion to reference certain subsets of defendants or defendants generally at trial. *See Flir Sys., Inc. v. Fluke Corp.*, No. 3:10-CV-00971-HU, 2012 WL 13054267, at *5 (D. Or. Nov. 29, 2012) ("It would be highly impractical to enforce this motion at trial. Absent a legitimate basis to preclude the use of a particular term . . . it is for counsel to choose the words they prefer to describe it.").

Further, any potential prejudice or confusion will be minimized through cross-examination and clarifying jury instructions. Distributor Defendants have not met their burden of demonstrating that the probative value of such testimony would be substantially outweighed by a risk of unfair prejudice. Distributor Defendants' MIL is an inappropriate method of addressing the word choice of Plaintiffs' counsel and witnesses, and should be handled by individual objections at trial. *See Stewart v. Hooters of Am., Inc.*, No. 8:04-CV-40-T-17-MAP, 2007 WL 1752873, at *1 (M.D. Fla. June 18, 2007) ("Motions In Limine are disfavored; admissibility questions should be ruled upon as they arise at trial.").

7. Distributors' MIL No. D-7: The Court should preclude Plaintiffs from offering evidence of, and arguments about RICO predicates that Plaintiffs did not identify in their discovery responses.

Distributor Defendants' MIL No. D-7 must be denied because it rests on a misapplication of the law and misstatements of the facts. Specifically, Distributor Defendants argue that the Court should exclude evidence of any racketeering activities not disclosed in Plaintiffs' discovery responses. But their cited authority does not support exclusion. Instead of addressing exclusion of evidence at trial after a purported failure to identify racketeering activities, Distributor Defendants' cases involve exclusion of evidence about legal claims alleged in a complaint or amended

complaint.[61] *See Bridgeport Music, Inc. v. WM Music Corp.*, 508 F.3d 394, 400 (6th Cir. 2007) ("Bridgeport's first amended complaint alleges liability on the part of Universal based solely on the inclusion of *Change Gone Come* in 'Well Connected' and 'Dead Man Walkin.' To the extent Bridgeport seeks to expand its claims to assert new theories, it may not do so in response to summary judgment or on appeal"); *Tucker v. Union of Needletrades, Indus., & Textile Emps.*, 407 F.3d 784, 787 (6th Cir. 2005) ("Tucker contends that the district court erred when it refused to consider her promissory estoppel claim. The court took this action after determining that she had neglected to include such a claim in her complaint"); *Vystrcil v. Mercy Health*, No. 17CV781, 2019 WL 2076035, at *4 (N.D. Ohio May 10, 2019) ("Plaintiffs argue that the April 7, 2017 telephone calls also violated 15 U.S.C. § 1692c(a)(2). Plaintiffs did not allege any violations of that subsection in the Amended Complaint. Plaintiffs may not expand the scope of their claims in an opposition to a summary judgment motion").

Here, setting aside the lack of authority regarding Distributor Defendants' position, their request for exclusion also fails because Plaintiffs identified the racketeering activities (and corrupt activities)[62] upon which they intend to rely at trial in their Complaints including: (1) mail fraud, (2) wire fraud; and (3) the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance. *See, e.g.,* Dkt. #1466 (Summit Third Amended Complaint) at ¶ 914. Indeed, Defendants made this same argument in the motion to dismiss phase of the case and the Court rejected it, confirming that each of the racketeering activities was sufficiently alleged. Dkt. #1025 at pp. 39-48; Dkt. #1203 at pp. 38-39. Plaintiffs did not identify any new racketeering activities in their opposition to Defendants' summary judgment motions.

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[61] *Feinstein v. Resolution Tr. Corp.*, is different than the above cases and even further afield because in *Feinstein*, the plaintiff failed to adequately plead the details of mail and wire fraud to overcome a Rule 9(b) argument. 942 F.2d 34, 42 (1st Cir. 1991) ("It is well settled in this circuit that Fed. R. Civ. P 9(b) . . . extends to pleading predicate acts of mail and wire fraud under RICO. . . . Neither in this part of the complaint nor in count 1 proper did the plaintiffs supply any additional details as to when the communications occurred, where they took place, or what they contained").

[62] Plaintiffs also identified telecommunications fraud as a corrupt activity in support of their OCPA claim. As this claim is not addressed in Distributor Defendants' motion, any ruling arising from it should not be applied to that aspect of Plaintiffs' OCPA claims.

Finally, Distributor Defendants' motion also fails because they mischaracterize Plaintiffs responses to their discovery requests. When asked to identify the racketeering activity at issue, Plaintiffs not only identified mail and wire fraud and violations of the CSA, including a broad range of misrepresentations and omissions that form the basis of those violations, they cited to documents supporting their claims. *See* **Ex. 16** [Plaintiffs' 12/14/18 Supplemental Objections and Responses to Distributor Defendants' Interrogatory Nos. 24, 25, 26, and 27]. In sum, Plaintiffs provided ample information to Defendants regarding the racketeering activity at issue and Defendants fail to provide any authority showing that more is required.

8. Distributors' MIL No. D-8: The Court should issue an order excluding any evidence of, or reference to, Distributor-run programs that allowed Manufacturers to communicate product information to Pharmacies or other parties.

Distributor Defendants seek to exclude evidence that Manufacturers use Distributors as a conduit to convey marketing information based on a misplaced argument under Rules 402 and 403. Dkt. #2666 at pp. 18-20. The evidence that Manufacturers used Distributors to market opioids is *not* being offered to support marketing-based claims against Distributors, but rather to demonstrate their overall motive and knowledge. Distributors profited from these marketing services and were aware of Manufacturers' marketing efforts and claims. This evidence is particularly relevant given Distributors' intent to blame Manufacturers, doctors, and patients as potentially superseding causes of Plaintiffs' injuries. The evidence further supports Plaintiffs' marketing RICO and conspiracy claims *against the Manufacturers*, as it is relevant to show how Manufacturers used their relationships with Distributors in order to further disseminate the Manufacturers' marketing messages.

In support of their erroneous arguments, Distributors misrepresent both statements made by Plaintiffs and the testimony of Plaintiffs' expert, Dr. Perri.[63] First, though Plaintiffs' conspiracy claims "*against the Pharmacy and Distributor Defendants* are not based on opioid marketing," Plaintiffs'

[63] Plaintiffs have not listed Dr. Perri as a testifying witness on their witness list, but mention him herein simply to correct Distributor Defendants' mischaracterization of his testimony in their motion.

RICO and Conspiracy claims against Manufacturers expressly *are*.[64] As discussed in Plaintiffs' summary judgment briefing, different coconspirators may have different roles in the conspiracy. Dkt. #2182 at p. 114-115. The evidence of Manufacturers' agreements with Distributors to use the Distributors to facilitate distribution of the Manufacturers' advertisements and marketing materials are directly relevant to Plaintiffs' claims *against the Manufacturers* who created the advertisements and who were well versed in the flaws in the marketing materials. Second, the testimony of Plaintiffs' expert Dr. Perri confirms that the Manufacturers' use of Distributors to convey the Manufacturers' marketing messages is an important fact in support of Plaintiffs' marketing claims, contrary to Defendants' inaccurate summary of Dr. Perri's testimony.[65]

Not only are these facts relevant to Distributors' motive and knowledge, as well as Plaintiffs' marketing claims against Manufacturers, such that exclusion under Rule 402 is not warranted, but they are hardly so prejudicial that they warrant exclusion under Rule 403. Any purported "spill over prejudice" may be resolved through jury instructions and does not warrant exclusion of this evidence. *See United States v. Fleming*, 902 F.2d 1570 (6th Cir. 1990) (evidence properly admitted where alleged "jury confusion and spill over prejudice were made less likely by the trial court's jury instructions."); *United States v. Mohammad*, No. 1:10CR389, 2012 WL 4483544, at *5 (N.D. Ohio, Sept. 27, 2012) (rejecting defendant's "spill-over prejudice argument" where "instructions to the jury directing them to consider the evidence and charges against each defendant separately" could "eliminate any possible prejudice"). Distributor Defendants' ill-founded MIL to exclude this evidence is due to be denied.

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64 Dkt. #2182 (Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO, and OCPA Claims) at p. 114 (emphasis added). *See also id.* at p. 114 ("the conspiracy began with the Manufacturer Defendants' false marketing efforts . . .), and pp. 7-27 (discussing the Manufacturers' marketing conspiracy).

65 Dkt. #1969-7/#1983-4 (4/23/19 Perri Dep.) at 217-222 (testifying that distributors were "integral" to manufacturers' functioning in the supply chain, that, in addition to conveying information on "price and availability" for the manufacturers, the distributors also conveyed marketing messages "beyond that" including "unbranded marketing messages," that "marketing behaviors … are interrelated" such that "the overall marketing and all the things [the defendants] did contributed to the marketing success," and that "the marketing of opioids was inappropriate" with the distributors being "part of that process").

C. PLAINTIFFS' RESPONSE TO HENRY SCHEIN DEFENDANTS' MOTIONS IN LIMINE (DKT. #2645).

1. Henry Schein MIL No. HS-1: References to the Henry Schein Defendants having engaged in any alleged activities with respect to Cuyahoga County.

Through MIL No. HS-1, the Henry Schein Defendants ("Henry Schein") seek a blanket prohibition of references to any Henry Schein entities or to "Defendants" or "Distributor Defendants" when referencing Plaintiff Cuyahoga County's claims because Cuyahoga did not sue the Henry Schein companies. Dkt. #2645 at p. 2. The Court should reject this request as both unwarranted and unworkable.

It is unwarranted because the mere fact that Cuyahoga did not sue Henry Schein does not mean *either* that Henry Schein's conduct in neighboring Cuyahoga County cannot be relevant to Plaintiff Summit County's claims against it *or* that Henry Schein's conduct as a non-party is irrelevant to Cuyahoga's claims. *See*, *e.g.*, *Stringer*, 749 F. Supp. 2d at 704 ("Minnesota courts have held that a third party's conduct is both relevant and sufficient to establish causation on a failure-to-warn claim."). For example, there is evidence that Henry Schein engaged in the "alleged activities" in Cuyahoga County since as early at 2010. A November 12, 2012 letter from HSI to the Ohio State Board of Pharmacy informs the Board that, with the exception of products containing two non-opioid substances, HSI failed to report sales of controlled substances as required by the state's Prescription Monitoring Program since as early as 2010. *See* Dkt. #2302-31/#2307-2 (Ex. 32 to Plaintiffs' Opp. to Non-Rico Small Distributors' MSJ). Defendants explain in the letter that HSI "operates six (6) distribution centers licensed to sell prescription drugs in Ohio. The primary customers for [their] distribution services are office based dental and medical practitioners." *Id.* Based on this language a reasonable juror could conclude that Henry Schein did distribute and fail to report the distribution of opioid products throughout the entire state of Ohio including Cuyahoga County from at least 2010-2012.

This MIL is also unworkable because this blanket requirement that any party not refer to "Defendants" or "Distributor Defendants" when discussing Cuyahoga's claims could not be enforced without an endless series of objections raised every time these words are spoken and

ensuing colloquies over whether the claims of Cuyahoga-only, Summit-only, or both were being discussed when the verboten word or words were spoken. Finally, a party's reference to "Defendants" or "Distributor Defendants" would not be prejudicial to Henry Schein under FED. R. EVID. 403 in any event because the jury may be instructed that Cuyahoga has no claims against Henry Schein and therefore it could not find Henry Schein liable to Cuyahoga. Henry Schein's MIL No. HS-1 therefore should be denied.

2. <u>Henry Schein MIL No. HS-2</u>: References to Henry Schein Medical Systems, Inc. as having distributed any opioid medications into Summit County or otherwise caused or contributed to any alleged opioid epidemic.

Henry Schein's MIL No. HS-2 addresses Defendant Henry Schein Medical Systems, Inc. ("HSMS") and seeks to prohibit Plaintiffs "from referencing HSMS as having distributed opioids generally or to Summit County specifically causing or contributing to any alleged opioid epidemic." Dkt. #2645 at p. 2. This request is contrary to Plaintiff Summit County's claims, *see* Dkt. #513 (Corrected 2d Am. Compl.) at ¶ 117 (HSMS's "symbiotic" arrangement with Defendant Cardinal Health generated hundreds of millions of dollars in sales), and to the Court's Order denying summary judgment for HSMS. Dkt. #2559 (Order Denying Small Distr. MSJ) at p. 5 ("[T]he Court is unable to conclude that no reasonable jury could find that Schein's market activities were *de minimus*."). Since sufficient evidence supports Summit's claims against HSMS, the Court should deny Henry Schein's MIL No. H-2 to preclude Plaintiffs from referencing Defendant HSMS as having caused harms to Summit County.

3. Henry Schein MIL No. HS-3: References to sales or distribution of opioid medications to retail, chain, Internet pharmacies, or "pill mills."

Neither Plaintiffs nor their counsel have any intention of making or eliciting factual misrepresentations at trial. Thus, if Defendant Henry Schein, Inc. ("HSI") truly did not distribute opioids to chain, retail, or internet pharmacies,[66] Plaintiffs and their counsel will not claim they did. To the extent Henry Schein believes that Plaintiffs have offered at trial specific evidence or argument on this issue that is factually inaccurate or lacks foundation, they should raise their objections at that time so that the Court can resolve the matter in context. A blanket motion *in limine* is not appropriate.

Henry Schein also inexplicably cites Federal Rule of Evidence 602 to support its conclusory argument that the "probative value of such references is contrary to the evidence, lacks foundation, and would otherwise confuse the jury and unfairly prejudice Henry Schein, Inc." Dkt. #2645 at p. 3. Rule 602 states:

> A witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may consist of the witness's own testimony. This rule does not apply to a witness's expert testimony under Rule 703.

FED. R. EVID. 602. It is not clear how this rule is relevant to MIL No. H-3, and Henry Schein provides no explanation. If Henry Schein has a Rule 602 objection to specific testimony, it should make that objection at trial.

For these reasons, Henry Schein's MIL No. H-3 should be denied.

4. Henry Schein MIL No. HS-4: References to opioid medications distributed by Henry Schein, Inc. to Dr. Brian Heim.

Henry Schein's MIL No. H-4 seeks to prohibit Plaintiffs from referencing HSI's distribution of prescription opioids to Dr. Brian Heim after he pled guilty and lost his medical license for felony

[66] Although Henry Schein claims that the "undisputed evidence shows that [HSI's] distribution of opioids in Summit County was limited to individual prescribers (*i.e.*, doctor and dentists)[,]" they failed to cite to, or attach, any such evidence to their motion *in limine*.

drug theft and again after he was indicted for drug trafficking, unless Plaintiffs show that the drugs sold were diverted. Dkt. #2645 at pp. 3-4.

The Court should reject this request as contrary to its recent Order denying summary judgment on causation. In that ruling, the Court rejected Defendants' argument that Plaintiffs must show whether each suspicious order shipped was in fact diverted, holding instead that:

> [G]iven the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs.

Dkt. #2561 (Order re MSJs on Causation) at p. 9. So it is here. Plaintiffs may introduce evidence of Henry Schein's sales to Dr. Heim after his guilty plea, loss of licensure, and later drug trafficking indictment as evidence of its complete failure to maintain effective controls *whether or not* those sales are shown to have been diverted. Henry Schein's MIL No. H-4 concerning Dr. Heim therefore should be denied.

5. <u>Henry Schein MIL No. HS-5</u>: References that Henry Schein, Inc. should not have shipped opioid medications following Dr. Heim's May 2012 indictment.

Henry Schein also seeks to exclude evidence regarding HSI's continued shipments of opioid medications to Dr. Heim after he was indicted in May 2012 for destroying business records and trafficking in the stimulant drug Adderall. Henry Schein argues that such evidence is inadmissible unless Plaintiffs can show HSI knew or should have known of the indictment.

As a distributor of dangerous drugs with a known risk of diversion, HSI had a duty to know and monitor their customers. For new customers seeking to purchase opioids, HSI should have exercised due diligence to determine whether there were any potential "red flags" with that new customer. HSI failed to adequately inquire about Dr. Heim's background when it approved him to purchase opioid medications. A simple verification of Dr. Heim's medical license in Ohio would have revealed that in 1998, Dr. Heim entered a guilty plea to twenty-four felony counts of theft of drugs and twenty-one felony counts of illegal processing of drug documents, which resulted in his

license being revoked. A reasonable distributor, knowing this information, would have realized that any sales to Dr. Heim would result in a likelihood of diversion and would have not sold opioid medications to him. From January 2010 to December 2011, Dr. Heim was listed as the 11th top prescriber of Oxycodone/APAP in the Akron, Ohio area, yet HSI's due diligence file for Dr. Heim does not reflect a single visit to his office.

Henry Schein designed and operated a grossly inadequate screening system for customers that allowed customers, including Dr. Heim, to place and receive large orders of opioids despite warning signs. HSI's witnesses repeatedly testified that their due diligence inquiry for opioid customers has never included either criminal background checks or medical license disciplinary checks. In this particular case, based on a license check HSI conducted in June of 2011, Henry Schein knew Dr. Heim had previously faced disciplinary actions. **Ex. 17** [HSI-MDL-00001198-HSI-MDL-00001210] at 1210. Despite this red flag, HSI made no additional effort beyond the license check and a simple questionnaire to determine whether Dr. Heim should be allowed to order and receive large quantities of opioids. In addition, Dr. Heim identified his areas of medical practice as Family Practice and Obstetrics & Gynecology. This should have been another red flag.

Instead, HSI shipped approximately 11,500 hydrocodone pills to Dr. Heim over fourteen transactions between August 17, 2011, and June 5, 2012. *See* Dkt. #2200 (Plaintiffs' Opp. to Non-RICO Small Distributors' De Minimis MSJ) at p. 10. Two thousand of those pills were shipped on May 21, 2012 and June 5, 2012, after Dr. Heim was indicted on May 18, 2012 for drug trafficking. Whether Henry Schein knew about the indictment at the time of the May and June shipments is irrelevant - they already had plenty of warning signs about Dr. Heim by that time. In addition, the orders Henry Schein filled for Dr. Heim were during the timeframe and of materials that were not reported to the Ohio Prescription Monitoring Program as previously discussed in above (*supra* at § C.1). Dkt. #2200 at p. 10. All of this information is relevant the question of Henry Schein's liability.

Had HSI performed the due diligence the law requires, it would have known about Dr. Heim's history of criminal activity. Consequently, HSI cannot claim ignorance of his indictment when minimal effort would have disclosed it. Henry Schein's MIL No. H-5 should be denied.

6. Henry Schein MIL No. HS-6: References to opioid medications distributed by Henry Schein, Inc. to Dr. Adolph Harper.

Henry Schein's MIL No. H-6 seeks to prohibit Plaintiffs from referencing HSI's distribution of opioids to Dr. Adolph Harper—who was convicted of drug trafficking, health care fraud, and conspiracy to distribute oxycodone, in effect operating a pill mill, and eight of whose patients died of overdose-related deaths—unless Plaintiffs show that the pills HSI sold to Dr. Harper were diverted. Dkt. #2645 at pp. 4-5.

The Court should reject this request, too, as contrary to its recent Order denying summary judgment on causation. In that ruling, the Court rejected Defendants' argument that Plaintiffs must show whether each suspicious order shipped was in fact diverted, holding instead that:

> [G]iven the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs.

Dkt. #2561 (Order re MSJs on Causation) at p. 9. So it is here. Plaintiffs may introduce evidence of HSI's sales to Dr. Harper as evidence of its complete failure to maintain effective controls. Although these sales pre-dated Dr. Harper's criminal conviction, the frequency and strength of the opioid prescriptions he wrote support Summit County's claim that Schein should have flagged his orders as suspicious. Dkt. #1999-7/#2000-7 (Keller Rep.) at ¶¶ 104-105. Henry Schein's MIL No. H-6 concerning Dr. Harper therefore should be denied.

7. Henry Schein MIL No. HS-7: References to purported inadequacies regarding Henry Schein, Inc.'s Suspicious Order Monitoring System without first identifying whether any orders that HIS sold into Summit County were diverted.

It is not entirely clear whether Henry Schein is arguing that evidence of HSI's insufficient

SOMS is itself irrelevant and unfairly prejudicial, or whether it is only irrelevant and unfairly prejudicial if Plaintiffs do not first demonstrate "that any of the opioid medications distributed by HSI into Summit County were diverted, or otherwise shown to have substantially caused or contributed to any public nuisance in Summit County." Regardless, both arguments are without merit. First, evidence of HSI's insufficient SOMS is highly probative to Plaintiffs' claims and is not unfairly prejudicial for the reasons discussed above as to Defendants' Omnibus MIL No. 7. *Supra* at § A.7. Additionally, Plaintiffs have already made an initial showing that Henry Schein's conduct substantially contributed to the public nuisance, which the Court considered sufficient to withstand summary judgment. Dkt. #2561 at p. 9 ("As with the SOMS claims against the Manufacturers, given the massive increases in the supply of prescription opioids into the *Track One* Counties, combined with evidence that suggests a complete failure by the Distributors and Pharmacies to maintain effective controls against diversion, a factfinder could reasonably infer these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs."); Dkt. #2559 (order denying small distributors' summary judgment motion). Plaintiffs understand that they will have to establish causation at trial, and fully intend to do so. Whether Plaintiffs have laid an adequate foundation for a particular piece of evidence or testimony is a determination that should be made at trial so that it can be resolved in context. *See Indiana Ins.*, 326 F. Supp. 2d at 846.

Finally, Henry Schein again inexplicably cites Federal Rule of Evidence 602 to support its conclusory argument that this evidence "lacks foundation and is otherwise irrelevant and unfairly prejudicial." Dkt. #2645 at p. 5. It is not clear how this rule, which requires witnesses to have personal knowledge of matters on which they testify (FED. R. EVID. 602), is relevant to MIL No. H-7, and Henry Schein provides no explanation. If Henry Schein has a Rule 602 objection to specific testimony, it should make that objection at trial.

For these reasons, Henry Schein's MIL No. H-7 should be denied.

8. <u>Henry Schein MIL No. HS-8</u>: References to alleged opioid medications distributed by Henry Schein, Inc. to locations outside Summit County.

Henry Schein's MIL No. HS-8 should be denied for the same reasons discussed above with

respect to Defendants' Omnibus MIL No. 6. *Supra* at § A.6.

9. Henry Schein MIL No. HS-9: References to DEA fines, investigations, or admonitions concerning Henry Schein, Inc.'s distribution of opioids to locations other than those in Summit County.

Henry Schein argues that evidence regarding fines imposed by other states is not relevant in this case because those fines did not involve HSI's distribution of opioids in Ohio. As discussed in § A.6, *supra*, however, Henry Schein's argument improperly seeks to limit the scope of Plaintiffs' proof. The opioid crisis and harm experienced by Cuyahoga and Summit Counties did not result solely from conduct by Defendants that specifically occurred in those counties or in Ohio. Rather, the problem caused in these counties by Defendants' oversupply, inadequate monitoring, and diversion resulted from conduct by Defendants that occurred all over the country. This issue is discussed more fully in response to Walgreens' MIL No. W-2, *infra* at § D.2, regarding a 2007 DEA enforcement action in Florida, which explains how Defendants' failures to adequately monitor sales to prevent diversion in one geographic location affects other locations, including the Plaintiff counties.

10. Henry Schein MIL No. HS-10: References to a purported 1998 cease and desist letter supposedly sent by Ohio Board of Pharmacy to Henry Schein, Inc.

Henry Schein seeks to exclude evidence regarding a "purported" letter "supposedly" sent in 1998 from the Ohio Board of Pharmacy to HSI. The MIL specifically references meeting minutes of the Ohio Board of Pharmacy from November 1998 that reference the letter. Henry Schein argues "[a]s an initial matter, there is no evidence that any such letter was actually sent to or received by HSI." Dkt. #2645 at p. 6.

Henry Schein is wrong. Its own documents reflect receipt of the very same letter referenced in the meeting minutes. In a PowerPoint presentation discussing HSI's due diligence requirements, there is a slide summarizing various "penalties" imposed by governmental entities on distributors, including HSI. The first item on the slide references a "Warning Letter" sent by the "Ohio State BOP" in 1998 to HSI regarding the "Sale of dangerous drugs to persons/entities not

licensed/authorized to possess them." **Ex. 18** [HSI-MDL-00176719] at p. 4. This could not be clearer. As has been discussed previously, this evidence is relevant and admissible to show that Henry Schein was aware that there were deficiencies in its oversight of sales of dangerous opioid medications, which is probative of its intent in causing the nuisance condition in Cuyahoga and Summit Counties.

11. Henry Schein MIL No. HS-11: References to alleged conduct supportive of Plaintiff's conspiracy claim, which took place, if at all, prior to May 18, 2014.

Henry Schein requests that Plaintiffs be prohibited from referencing, or introducing evidence of, Henry Schein's pre-May 18, 2014 conduct to support their conspiracy claim. In support, Defendants argue "Plaintiff has acknowledged that its conspiracy claim against the Henry Schein Defendants…is governed by a four (4) year statute of limitations." Dkt. #2645 at p. 7. This argument is not only unsupported in the motion, it is simply not true. Henry Schein's MIL No. HS-11 should be denied for multiple reasons.

First, as Plaintiffs argued and the Court has held, there is no statute of limitations for Plaintiffs' RICO claims for equitable relief and they "are exempt from the operations of a limitations period." Dkt. #2568 at p. 11. Second, to the extent Defendants contend that a four year statute of limitations is applicable to Plaintiffs' public nuisance claim, Plaintiffs have consistently argued there is no limitations period applicable to public nuisance claims. More importantly, this Court also held there is no limitations period for absolute nuisance claims. *Id.* at p. 5. Third, since "the applicable statute of limitations for filing a civil conspiracy cause of action is the relevant limitations statues for the underlying cause of action," *id.* at p. 12 (citation omitted), and the underlying cause of action is public nuisance there is likewise no conspiracy statute of limitations at issue here. Fourth, as set forth in Plaintiffs' prior arguments submitted in opposition to the Defendants' motion for partial summary judgment on statute of limitations grounds, pre-May 18, 2014 conduct remains relevant and admissible as it relates to post-May 18, 2014 damages and liability. Dkt. #2212 at pp. 55-56. Indeed, unless Henry Schein demonstrates that it has *affirmatively withdrawn* from a conspiracy, it remains exposed to liability for post-May 18, 2014 damages for the acts of its co-conspirators. To

the extent Henry Schein seek to temporally limit the scope of its participation in the conspiracy, it has not pointed to any action taken to affirmatively withdraw from the conspiracy.[67]

Finally, this Court held that there are "material fact questions concerning the claim's accrual dates, whether Plaintiffs exercised reasonable diligence to discover facts necessary to bring suit, and the applicability of tolling doctrines." Dkt. #2568 at p. 1; *see also* Dkt. #2212. The Court further ruled that questions about "the dates these [civil conspiracy] claims accrued or the periods they were tolled," can only be answered after a presentation of all the evidence at trial. Dkt. #2568 at p. 3.

There are multiple factual disputes involving Henry Schein the jury will need to consider. For example there is evidence that, despite recommendations to the contrary, Henry Schein willfully failed to design a system that would detect suspicious orders until at least October 2009.[68] In addition, there is evidence that Henry Schein failed to report suspicious orders to the DEA when discovered until at least 2017 and that, in the meantime, Henry Schein was aware it lacked due diligence files for 27,000 customers.[69] Whether and the extent to which these actions impact the statute of limitations and/or the date(s) Plaintiffs' claims accrued must be determined at trial.[70]

Henry Schein's MIL No. HS-11 should be denied for these reasons.

12. <u>Henry Schein MIL No. HS-12</u>: References to Henry Schein Animal Health, which is not a named party to Plaintiff's lawsuit.

Henry Schein's MIL No. HS-12 seeks to prohibit any reference to or evidence concerning Henry Schein Animal Health ("HSAH"), which is not a named defendant. Dkt. #2645 at pp. 7-8.

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67 "[O]nce a conspiracy has been established, it is presumed to continue until there is an affirmative showing that it has been abandoned." *Watson Carpet & Floor v. Mohawk Indus.*, 648 F. 3d 452 (6th Cir. 2011). "At a minimum, 'affirmative acts inconsistent with the object of the conspiracy and communicated in a manner reasonably calculated to reach co-conspirators [are] sufficient to establish withdrawal or abandonment." *In re Cathode Ray Tube Antitrust Litig.*, MDL 1917, Case No. C-07-5944 JST, 2016 WL 8669891, *3 (N.D. Cal. 2016) (citing *U.S. v. U.S. Gypsum Co.*, 438 U.S. 422, 464-5 (1978)).

68 *See* Dkt. #1956-2 (12/13/18 Abreu Dep.) at 237:21-239:1, 259:17-261:19, 454:12-456:24.

69 *Id.* at 261:9-19, 294:21-295:7, 308:10-310:24.

70 Dkt. #2568 at p. 3.

Henry Schein asserts that any reference or evidence about HSAH "is irrelevant as to whether HSI or HSMS substantially caused or contributed to the alleged public nuisance in Summit County. *Id.* at p. 7. This is incorrect. An entity's status as a non-party is not determinative of whether its conduct is relevant to a claim. *See*, *e.g.*, *Stringer*, 749 F. Supp. 2d at 704 ("Minnesota courts have held that a third party's conduct is both relevant and sufficient to establish causation on a failure-to-warn claim.").

Here, Plaintiffs allege that HSAH was investigated for distribution of wholesale dangerous drugs to an unlicensed entity in Ohio in 2014. Dkt. #513 (Corrected 2d Am. Compl.) at ¶ 590. Although Defendant HSI asserts that it "no longer holds an interest" in HSAH, Dkt. #2645 at p. 7, it does not dispute that it did when the conduct at issue took place. Henry Schein's request concerning HSAH therefore is either baseless or else premature. *See*, *e.g.*, *Hochstein v. Microsoft Corp.*, 04-73071, 2009 WL 2022815, at *6 (E.D. Mich. July 7, 2009) (denying motion *in limine* to exclude "any reference to third party games for which discovery was not sought" as "premature," to which the parties agreed). In either event, Henry Schein's MIL No. H-12 should be denied.

D. PLAINTIFFS' RESPONSE TO WALGREENS' MOTIONS *IN LIMINE* (DKT. #2648).

1. <u>Walgreens' MIL No. W-1</u>: To preclude evidence or argument about Walgreens' ownership interest in AmerisourceBergen.

Walgreens's argument that evidence of its ownership interest in AmerisourceBergen should be excluded under Rules 402 and 403 is based on a misconstruction of the purpose for which Plaintiffs propose to rely on the evidence. Plaintiffs do not seek to hold Walgreens liable for the actions of AmerisourceBergen as a legal control person or parent entity. Rather, Plaintiffs seek to enter evidence of Walgreens' ownership interest in AmerisourceBergen as being relevant to Plaintiffs' conspiracy claims.

The financial relationships between Defendants, including Walgreens's ownership interest in AmerisourceBergen, are relevant to show the continuing conspiracy among the Defendants and should not be excluded under Rule 402. Plaintiffs' summary judgment briefing concerning Plaintiffs' RICO and conspiracy claims set out the significant financial interests implicit in the

relationships among and between the Defendant coconspirators. *See, e.g.,* Dkt. #2182 at pp. 63-68. This evidence of Defendants' financial interests and connections is relevant to Plaintiffs' conspiracy claims. *See United States v. Robinson*, 763 F.2d 778, 783 n.8 (6th Cir. 1985) ("evidence tending to establish. . . . an ownership interest . . . would be relevant as tending to show . . . a motive for entering into the conspiracy"); *United States v. Gupta*, 747 F.3d 111, 139 (2d Cir. 2014) (evidence establishing ownership were relevant to establish "financial stake in the profitability" of an entity in context of alleged conspiracy); *Cadence Educ., LLC v. Vore*, No. 17-CV-2092-JTM-TJJ, 2018 WL 690993, at *7 (D. Kan. Feb. 2, 2018) (defendants ordered to produce documents concerning ownership interest in corporate entities and relationships between corporate entities as being relevant to conspiracy claims).

Walgreens has repeatedly taken the position that its liability ended when it ceased self-distribution. However, as set out in Plaintiffs' summary judgment briefing regarding Plaintiffs' conspiracy claims, Walgreens did not withdraw from the Conspiracy at that time – or ever – and has continued to work with other Defendants, including AmerisourceBergen, to continue to support the conspiracy's objectives. Dkt. #2182 at pp. 116-117. Walgreens remains liable for the actions of its coconspirators in furtherance of the conspiracy, regardless of its cessation of distribution. The jury should be permitted to consider Walgreens' near simultaneous decision to stop self-distribution, entry of an exclusive distribution relationship with coconspirator AmerisourceBergen, its corporate involvement in the AmerisourceBergen SOM review of Walgreens orders, and the beginning of Walgreens acquisition of significant amounts of AmerisourceBergen stock, which also provided Walgreens with a seat on AmerisourceBergen's Board.

Walgreens's continued participation in the conspiracy and financial relationships to conspirators are relevant to show Walgreens's continued corporate involvement in and support of the conspiracy, including Walgreens's involvement in the SOM procedures applied by AmerisourceBergen to orders for prescription opioids placed by Walgreens's pharmacies, and do not transform Plaintiffs distribution and conspiracy based claims into claims based on Walgreens pharmacy level dispensing. Walgreens' MIL No. W-1 should be denied.

2. Walgreens' MIL No. W-2: To preclude evidence or argument about Walgreens' Florida DEA enforcement action and related settlement.

The arguments asserted by Walgreens regarding admissibility under Rule 408 and 403 are addressed in § B.1, *supra*. Rule 408 does not preclude this evidence, and it is both relevant and not unfairly prejudicial.

With regard to Walgreens' argument that evidence concerning the Florida DEA enforcement action should be excluded because it occurred in Florida, rather than Ohio, this argument ignores the well-known problem of opioid "migration" from one location to another. As the Washington Post recently reported,

> During the past two decades, *Florida became ground zero for pill mills* — pain management clinics that served as fronts for corrupt doctors and drug dealers. They became so brazen that some clinics set up storefronts along I-75 and I-95, advertising their products on billboards by interstate exit ramps. So many people traveled to Florida to stock up on oxycodone and hydrocodone, they were sometimes referred to as "prescription tourists."
>
> *The route from Florida to Georgia, Kentucky, West Virginia and Ohio became known as the "Blue Highway."* It was named after the color of one of the most popular pills on the street — 30 mg oxycodone tablets made by Mallinckrodt, which shipped more than 500 million of the pills to Florida between 2008 and 2012.
>
> When state troopers began pulling over and arresting out-of-state drivers for transporting narcotics, drug dealers took to the air. *One airline offered nonstop flights to Florida from Ohio and other Appalachian states, and the route became known as the Oxy Express.*

"76 billion opioid pills: Newly released federal data unmasks the epidemic," The Washington Post, July 16, 2019 (emphasis added).[71]

There is abundant evidence in the record – including in Walgreens' own internal documents – that the opioids the Defendants shipped migrated far beyond the borders of the states to which the shipments were made, including, oftentimes, to Ohio, and that Defendants were well aware of this phenomenon. *Supra* at fn.37. Defendants were regularly alerted to the migration phenomenon

[71] *Available at* https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html (accessed on 10/3/19).

by the DEA, and their personnel acknowledged the reality of diversion and migration in their depositions. *Supra* at fns.39-40.

Against this robust record of diversion and migration, of which the above-cited materials are only examples, Walgreens' assertion of the lack of a nexus between their irresponsible shipment practices and harm to the CT-1 Plaintiffs rings hollow. Defendants shipped hundreds of millions of opioid pills to resellers throughout the U.S. They knew that those resellers could, and often did, sell those opioids to individuals who had come long distances from Ohio or elsewhere to obtain pills they could in turn sell at a substantial profit back home. That every diverted pill posed a risk to localities throughout the nation was not only foreseeable to Walgreens, it was observed and known by them. Each shipment Walgreens made in disregard of the potential for diversion is evidence of damages caused by Walgreens to localities throughout the nation, including Cuyahoga and Summit Counties.

Because the potential for diversion is so great and its consequences so pernicious, each Defendant was required to establish and maintain a SOM program. Plaintiffs have catalogued the numerous flaws in the SOMs operated by Defendants. Each Defendant's SOM was implemented nationally; no special procedures were followed with respect to the CT-1 jurisdictions or elsewhere. Because of the uniform national character of Defendants' SOMs, each wrongful order filled by Defendants is further evidence of the flaws in Defendants' SOMs, and of the consequences of those flaws. Defendants' efforts to exclude this highly probative evidence, including by Walgreens' MIL No. W-2, should be denied.

3. Walgreens' MIL No. W-3: To preclude, e.g., evidence or argument referring to DEA witness Joseph Rannazzisi as the "60 Minute Man."

Walgreens' motion to preclude evidence or argument that former DEA Deputy Administrator Joseph Rannazzisi's credibility is bolstered by his appearance on "60 Minutes," or by reporting by other news outlets, has no merit. Walgreens specifically seeks to preclude such references – and in particular, reference to Mr. Rannazzisi as the "60 Minute Man" – on the grounds that such references would invade the jury's role as factfinder, as well as mislead and confuse the jury. These purported concerns cannot be taken seriously.

First, Walgreens' objection to the specific phrase "60 Minute Man" – to reference a man who appeared on "60 Minutes" – has no legal basis. The parties have listed hundreds of names to appear as potential witnesses at trial, and each witness called by the parties will testify in varying levels of detail as to their backgrounds, educational history, employment history, as well as their involvement and interactions with the opioid epidemic. Brief, accurate references to a relevant and undisputed part of a witness's history are thus necessary at trial. Instead of reciting a witness's full name, full job title, and dates of employment, counsel routinely instead refers to "the Walgreens' CEO," "the ABDC Consultant," or "the Mallinckrodt Investigator." "The 60 Minute Man" is no different, and this phrase includes no commentary or argument as to Mr. Rannazzisi's credibility. It simply references a critical part of one witness's relevant history in a neutral, shorthand phrase. Forbidding such references at trial would result in bizarre affirmative rules mandating the use of each witness's full name and title each time counsel references that witness. Walgreens' request here is unreasonable and untenable, and must be denied.

Second, actual references to Mr. Rannazzisi's credibility in connection with either his "60 Minutes" interview, or other news reports, do nothing to invade the jury's role as a factfinder to weigh the strength of the evidence. In fact, such references affirmatively provide additional evidence for the jury to weigh. With this evidence – and any admissible impeachment evidence offered by Defendants – the jury is free to determine whether it finds Mr. Rannazzisi to be a

credible witness.[72] Indeed, a reputable news outlet's use and reliance on Mr. Rannazzisi's comments in a national broadcast or publication constitutes valid and admissible evidence of his credibility. And Walgreens cites no authority that such evidence is typically excluded.

Finally, references to Mr. Rannazzisi's credibility in connection with either his "60 Minutes" interview, or other news reports, also do nothing to mislead or confuse the jury. The decision of various news outlets to broadcast and publish Mr. Rannazzisi's statements is useful information the jury should consider in weighing the strength of his testimony. This inference does not mislead the jury as to any facts (and Walgreens identifies none), nor does it confuse the jury as to any facts (and Walgreens identifies none). Walgreens' MIL No. W-3 should accordingly be denied.

E. PLAINTIFFS' RESPONSE TO CARDINAL HEALTH INC'S MOTIONS *IN LIMINE* (DKT. #2653).

1. Cardinal MIL No. 1: 14,000 Orders Not Shipped.

Cardinal erroneously seeks to exclude evidence that it failed to report more than 14,000 suspicious orders nationwide under Rule 402 and pursuant to a misplaced and repeatedly rejected preemption argument. Dkt. #2653-1 at pp. 1-4. Cardinal's MIL is due to be denied on both grounds.

Cardinal's admitted failure to report suspicious orders is relevant to Plaintiffs' claims that Cardinal failed to maintain effective controls against the diversion of opioids. This evidence presents another example of Cardinal's failures both in CT1 counties specifically and nationally. Even after the DEA took action against Cardinal in 2008 and 2012, Cardinal continued to fail to establish an effective SOM program. Over at least six years[73] Cardinal was failing to report

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[72] *See U.S. v. Turning Bear*, 357 F.3d 730 (8th Cir. 2004) (admitting evidence of witness's character for truthfulness over Rule 403 objection, that was neither substantially outweighed by unfair prejudice nor needlessly cumulative, where credibility of the testimony was at issue); *U.S. v. Lopez-Ortiz*, 736 F. Supp. 2d 469, 471 (D.P.R. 2010) ("Allowing defense counsel to introduce admissible testimony or other evidence bearing on the government witnesses's character would not result in unfair prejudice to the government's case or unfairly influence the jury.").

[73] Cardinal told the DEA that the "vast majority" of the unreported suspicious orders were placed during the time period of 2012-2015, but that 23 have occurred since January 1, 2017. **Ex. 19** [CAH_MDL2804_02101803].

suspicious orders of the most highly abused opioids and only disclosed their failures in 2018 because of pending litigation with an attorney general.

The seriousness of Cardinal's failure to report these suspicious orders is underscored by the fact that, according to Cardinal, the "vast majority" of the suspicious orders were for formulations of opioids most likely to be diverted and abused.[74] Cardinal sets sub-base code thresholds only for the most highly abused strengths of certain opioids. These formulations, according to Cardinal, "are more susceptible to diversion and abuse," including in particular 15 and 30 milligram doses of oxycodone and 10 milligram doses of hydrocodone.[75] If it was not egregious enough that Cardinal failed to report thousands of suspicious orders over the course of at least six years, the fact that most of those orders were for the most dangerous versions of opioids is astounding given the company's history with DEA administrative actions. The unreported suspicious orders are directly relevant to whether Cardinal was able to maintain effective controls against diversion after 2012.

While Cardinal contends that four of the more than 14,000 unreported suspicious orders originated from Summit and/or Cuyahoga Counties, Cardinal advised the DEA that 887 of the orders were placed by customers in the Wheeling, West Virginia Distribution Center's service area, which includes Summit and Cuyahoga Counties.[76] Even if the orders were not shipped, it is undisputed that pharmacies in this region placed nearly 900 suspicious orders, the vast majority of which were for the most abused and diverted opioids.[77] Cardinal's failure to report allows these bad pharmacies to continue to operate without further investigation.

Cardinal attempts to downplay the number of suspicious orders it failed to report by stating that it was reporting "tens of thousands of orders a year" from 2012 to 2015. However, in his 2012 Annual Quality and Regulatory Report to the Cardinal Board of Directors' Audit Committee, Chief

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74 *Id.*

75 **Ex. 20** [CAH_MDL2804_00069435] at 48.

76 **Ex. 19** [CAH_MDL2804_02101803] at 4.

77 Dkt. #1959-14 (9/26/18 Cameron Dep.) at 269:12-270:13 (produced at CAH_MDL2804_02953369); **Ex. 20** [CAH_MDL2804_00069435] at 48.

Legal and Compliance Office Craig Morford reported that Cardinal had reported only 3,020 suspicious orders to the DEA nationwide in fiscal year 2012.[78] The ratio of unreported suspicious orders versus reported suspicious orders is much larger than Cardinal presents.

Finally, Cardinal recycles again here the preemption arguments this Court has repeatedly rejected.[79] Those arguments are made no more persuasive in their third iteration. Cardinal's MIL No. 1 should be denied.

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78 **Ex. 21** [CAH_MDL2804_03262274] at 438.

79 Dkt. #1025 (Report and Recommendation) at pp. 48-54 (rejecting preemption arguments); Dkt. #1203 (Opinion and Order) at p. 2 (adopting R&R decision on preemption); Dkt. # 2565 (Opinion and Order re: Preemption) (rejecting all preemption arguments).

2. Cardinal MIL No. 2: "Interesting Gossip" Email.[80]

Cardinal bases its argument that MCKMDL00545341 should be excluded under Rules 402 and 403 (Dkt. #2653-1 at p. 4) on a misconstruction of the purpose for which Plaintiffs propose to use the email at trial. The email, and the notes attached thereto, contain the report from Cardinal's Director of Regulatory Affairs of a "Huddle" meeting among Cardinal, McKesson, AmerisourceBergen, and HD Smith (the self-styled "Big Four") and the issues discussed therein, including those related to CSA compliance. Plaintiffs do not intend to cite the email as evidence that Cardinal failed to report suspicious orders, but rather as evidence of the nature of the relationships between these Defendants and the types of CSA compliance related issues they discussed and coordinated together.[81]

The evidence is relevant and should not be excluded under Rule 402. The email Cardinal moves to exclude contains notes from a Big Four "Huddle" meeting that occurred during and after an HDA conference. During this Huddle, these Defendants all discussed CSA compliance issues, including intentional failure to comply. This document (among others) shows that Big Four Huddles in conjunction with HDA conferences occurred and further shows the kinds of discussions that occurred at the meetings. This evidence is particularly relevant to Plaintiffs' RICO and conspiracy claims because it shows, as Plaintiffs' alleged in their TAC,[82] that Defendants used the HDA as a forum in which to form agreements, to discuss issues related to suspicious order compliance, and to coordinate their activities. The document is also relevant to show Defendants' knowledge of – and failure to report - the noncompliance of direct competitors. Moreover, the

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80 Though Cardinal's motion refers to MCKMDL0054341, based on the first page of the email, which Cardinal attaches to the motion, and the context of the argument, Plaintiffs believe Cardinal made a typographical error and respond regarding MCKMDL00545341. Further, Cardinal only includes the cover page of MCKMDL00545341 as an exhibit to its motion, depriving the Court of the full context of the document. Plaintiffs attach the complete document – including the attached notes – here. *See* **Ex. 22** [MCKMDL00545341-347].

81 The purpose for which Plaintiffs intend to offer the email is confirmed in Plaintiffs' omnibus summary judgment opposition briefing regarding Plaintiffs' Conspiracy, RICO, and OCPA claims (Dkt. #2182 at pp. 37 and Exhibit 291).

82 *See* Dkt. #1466 (Summit Third Amended Complaint) at ¶¶ 540-546, 763-767, 854, 910.

"interesting gossip" section of the Huddle notes is also relevant to show that the relationships between these Defendants were so secure that Cardinal felt comfortable disclosing intentional regulatory violations.

Rule 403 does not justify exclusion of the Big Four Huddle document. While all evidence is prejudicial, Rule 403 requires that the probative value of the document be outweighed by the prejudice. *See Koloda v. General Motors Parts Div., General Motors Corp.*, 716 F.2d 373, 378 (6th Cir. 1983) ("Virtually all evidence is prejudicial or it isn't material. The prejudice must be 'unfair.'"). Exclusion under Rule 403 is an "extraordinary remedy and carries a strong presumption in favor of admissibility." *In re Air Crash at Lexington, KY*, No. 5:06-CV-316-KSF, 2008 WL 2782827, at *1 (E.D. Ky. July 8, 2008) (citing *U.S. v. Grant*, 256 F.3d 1146, 1155 (11th Cir. 2001). *See also In re Air Crash Disaster*, 86 F.3d 498, 538 (6th Cir. 1996) ("Rule 403 does not exclude evidence because it is strongly persuasive or compellingly relevant—the rule only applies when it is likely that the jury will be moved by a piece of evidence in a manner that is somehow unfair or inappropriate. The truth may hurt, but Rule 403 does not make it inadmissible on that account."). Here, there are multiple reasons why this Big Four Huddle document has probative value regarding the defenses and claims at issue in this case, as discussed above. Cardinal's only argument about prejudice is their presumption (without supporting evidence) that the document contains an allegedly inaccurate statement that would require rebuttal and take time. Cardinal's position is simply not enough to overcome the significant probative value of the Big Four Huddle document. Cardinal's MIL No. 2 should be denied.

3. <u>Cardinal MIL No. 3</u>: Misleading Data Comparisons (McCann Data Analysis).

Cardinal seeks to prohibit Plaintiffs' expert Dr. Craig McCann from testifying based upon data produced by Cardinal for the years 1996-2005. Cardinal argues that because it retained and produced data for several years prior to the period covered by other Distributor Defendants' productions, the jury may be confused when comparing Dr. McCann's opinions regarding Cardinal to his opinions regarding the other Distributor Defendants. Plaintiffs dispute Cardinal's contentions

regarding the potential for juror confusion and do not believe any limiting instruction is necessary. Should the need arise for any clarification, Defendants can make a request for a properly worded instruction at the time the evidence is offered and a determination as to the appropriateness of said instruction can be made at that time.

F. PLAINTIFFS' RESPONSE TO MCKESSON CORPORATION'S MOTION IN LIMINE TO EXCLUDE CERTAIN EVIDENCE AND ARGUMENT (DKT. #2663).

1. McKesson MIL No. MCK-1: The Court should prohibit any reference to baseless accusations.

McKesson asks the Court to prohibit Plaintiffs from making "baseless accusations." Dkt. #2663-1 at p. 1. This request is one part specific, and one part general. As to the general, of course, Plaintiffs do not believe their allegations of McKesson's widespread and rampant misconduct are baseless, and indeed, the parties' disagreement on this score is the reason for the trial. Thus, McKesson's vague request that Plaintiffs be precluded from referencing "unfounded accusations" in "opening, closing, or during examination of witnesses" should be rejected. Dkt. #2663-1 at p. 2.

As to the specific, McKesson complains about certain deposition questions regarding former Attorney General Eric Holder. Plaintiffs dispute that the questions were baseless, but this testimony was not designated by Plaintiffs for trial, and so the request to strike reference to them is now moot. McKesson also complains about deposition questions pertaining to whether McKesson Chief Executive Officer John Hammergren knowingly provided false information during Congressional testimony when he stated that McKesson did not market opioids to, among others, pharmacists. *Id.* This is an entirely appropriate area of inquiry in light of McKesson's marketing agreements with other Defendants, including Teva, Purdue, and Actavis. *See, e.g.*, Dkt. #2169-32/#2173-50 (7/19/18 Oriente Dep.) at 278-287, 305-313. McKesson has every right to argue that Hammergen's testimony was the whole truth, but Plaintiffs have the equal right to present witnesses with evidence that suggests otherwise and question the bases of McKesson's public statements. *See, e.g., Goldman,* 559 F. Supp. 2d at 871 ("Factual questions should not be resolved through motions in limine.").

For these reasons, McKesson's MIL No. MCK-1 should be denied.

2. <u>McKesson MIL No. MCK-2</u>: The Court should prohibit evidence or argument about the U.S. House of Representatives Energy and Commerce Committee's Investigation.

McKesson's MIL No. MCK-2 seeks to preclude Plaintiffs from offering evidence or argument regarding the U.S. House of Representatives Energy and Commerce Committee's Investigation. Dkt. #2663-1 at p. 2. This MIL should be denied for the following reasons.

i. The House Report is admissible under Rule 803(8) because it is factual findings from a legally authorized investigation and there are no indications of untrustworthiness.

The U.S. House of Representatives, Committee on Energy and Commerce Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia* (the "House Report") (**Ex. 23**) clearly is admissible under Rule 803(8) of the Federal Rules of Evidence. Rule 803(8) provides, in relevant part:

> A record or statement of a public office [is not excluded by the rule against hearsay] if . . . it sets out . . . in a civil case . . . factual findings from a legally authorized investigation[,] and . . . the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness.

FED. R. EVID. 803(8). Rule 803(8) is intended to encompass investigative or "evaluative reports" generated in the course of a public agency's duties. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 166 (1988). Examples of the types of agency investigative reports admissible under Rule 803(8) include accident reports prepared by specialized agencies, consumer safety studies, and diagnostic studies relating to issues of public health.[83] Conclusions and opinions, as well as facts, are admissible under Rule 803(8) as long as they are based on a factual investigation and satisfy the Rule's trustworthiness requirement. *Beech Aircraft*, 488 U.S. at 170.

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[83] *See, e.g., id.* at 170 (Air Force accident report on cause of plane crash in training exercise); *United States v. Midwest Fireworks Mfg. Co.*, 248 F. 3d 563, 566-67 (6th Cir. 2001) (reports of Consumer Product Safety Commission); *O'Dell v. Hercules, Inc.*, 904 F. 2d 1194, 1204-06 (8th Cir. 1990) (CDC report on health risks from environmental exposure to dioxin).

In light of this presumption of admissibility, the party opposing the admission of the report must prove that the report is not trustworthy. *Baker v. Elcona Homes Corp.*, 588 F.2d 551, 558 (6th Cir. 1978), *cert. denied*, 441 U.S. 933 (1979). To determine whether a report is trustworthy, courts consider the following four factors: (1) the timeliness of the investigation upon which the report is based, (2) the special skill or experience of the investigators, (3) whether the agency held a hearing, and (4) possible motivational problems. *Bank of Lexington & Trust Co. v. Vining–Sparks Sec., Inc.*, 959 F.2d 606, 616–17 (6th Cir. 1992). McKesson has failed to show that the House Report lacks trustworthiness under any of these factors.

The House Report was the result of an in-depth, bipartisan investigation into the distribution of prescription opioids by wholesale distributors, which was undertaken as part of the Committee's legislative responsibilities. The report itself contains factual findings. The Subcommittee on Oversight and Investigations held hearings and received sworn testimony from, and posed questions to, representatives of each of the wholesale drug distributors involved in the investigation. The Subcommittee examined the role that each company may have played in contributing to the opioid epidemic. In addition, the five distributors (Cardinal Health, AmerisourceBergen, McKesson, Miami-Luken and H.D. Smith) provided thousands of pages of documents to the Committee, including due diligence files, suspicious order reports and policy manuals. **Ex. 23** [House Report] at p. 40. In all, the Committee, through its members and staff, sent twelve letters requesting documents and information, reviewed more than 20,000 pages of material obtained from the DEA and wholesale distributors, participated in numerous briefings with the DEA and wholesale distributors, and held two hearings. *Id.* at pp. 43-44.

McKesson bases its challenge on possible motivational problems, arguing that the investigation was "highly charged" and involved matters already a subject of litigation (and thus subject to influence by the litigants). Dkt. #2663-1 at p. 2. The cases McKesson cites for its proposition mostly involve draft reports and partisan investigations.[84] In contrast, here the House

[84] *See Anderson v. Westinghouse Savannah River Co.*, 406 F.3d 248, 264 (4th Cir. 2005) (affirming exclusion on the grounds that "the Department of Energy's assessment was only a draft report"); *Pearce v. E.F. Hutton*

Report is a final report which resulted from a bipartisan investigation. Where, as here, members of both parties joined in the report, courts have been more likely to reject challenges to the admissibility of Congressional reports.[85] McKesson has not pointed to anything in either the House Report or the hearings that would indicate that the report was prepared primarily or even partially to assist in ongoing opioid-related litigation. McKesson alleges that Plaintiffs' counsel in this litigation played an active role in the investigation process, including by briefing congressional staff and providing them with "factsheets" about the opioid epidemic. Dkt. #2663-1 at p. 2 n.4. McKesson fails to state that Defendants also had input into the investigation, including briefing congressional staff and providing documents and testimony. **Ex. 24** [MCKMDL00373829]; **Ex. 25** [ABDCMDL00320377]; **Ex. 26** [CAH_MDL_PRIORPROD_HOUSE_0004057]; **Ex. 27** [CAH_MDL_PRIORPROD_HOUSE_0004068]; **Ex. 28** [ABDCMDL00321879]; **Ex. 29** [MCKMDL00373814].

ii. The findings of the House Report are probative into the issues at the core of the claims in this case and its inclusion is unlikely to unfairly prejudice the jury.

The investigation that led to the House Report sought to "evaluate the extent that distributors implemented controls to prevent diversion of opioids." **Ex. 23** [House Report] at p. 4. Further, while the House Report "focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide." *Id.* at p. 9. The House Report notes that its findings "raise questions about the effectiveness of distributors' anti-diversion efforts outside West Virginia, as the same policies were implemented across the country." *Id.* at p. 105. Thus, the House Report's probative value is not limited to conduct that occurred in West

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Group, Inc., 653 F. Supp. 810, 813–15 (D.D.C. 1987) (excluding House committee report that was "dissented to directly along party lines" and that failed "to isolate or distinguish any factual findings from its subjective criticisms and conclusions").

85 *See McFarlane v. Ben–Menashe,* No. 93–1304, 1995 WL 129073, at *4–*5 (D.D.C. March 16, 1995) (admitting the report of a joint Congressional task force in which members of both parties joined), *reconsideration granted on other grounds,* 1995 WL 799503 (D.D.C. June 13, 1995); *Hobson v. Wilson,* 556 F. Supp. 1157, 1181 (D.D.C. 1982) (admitting committee report that "reflected adherence to appropriate standards of scholarly responsibility, investigative integrity, and trustworthiness"), *aff'd in part, rev'd in part on other grounds,* 757 F.2d 1 (D.C. Cir. 1985).

Virginia. The House Report is directly relevant to the litigation, going to Defendants' due diligence, suspicious order monitoring and reporting practices. Further, Defendants' own experts relied on the House Report and it was included on at least one Defendant exhibit list.[86]

Thus, there is no doubt that this evidence is highly probative on a number of issues and Defendants have not met their burden to demonstrate a risk of prejudice, much less a risk that is so substantial that outweighs their probative value.

iii. Testimony Provided to the Committee is Also Admissible.

McKesson also challenges the admissibility of testimony given by McKesson Chairman, President and CEO John Hammergren to the Subcommittee on Oversight and Investigations Committee on Energy and Commerce United States House of Representatives. The statements made by Mr. Hammergren were made while he was the McKesson Chairman, President and CEO of McKesson and related to McKesson's role in the supply chain and its SOM system, unquestionably matters within the scope of his employment. These statements are therefore admissible as party admissions under Rule 801(d)(2)(D) of the Federal Rules of Evidence. Additionally, to the extent that Defendants' experts relied on this testimony it is relevant to challenge their opinions.[87]

iv. Letters from members of Congress to McKesson Are Admissible.

McKesson argues that the February 15, 2018 letter sent from members of Congress to McKesson is inadmissible hearsay. However, the letter to McKesson is not offered to prove the truth of the matters asserted in the letter, but rather as background for the House investigation and to show McKesson's awareness of the investigation and that the statements in the letter were

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86 *See* Dkt. #2174-2/#2172-2 (Bell Expert Rep.) at p. 70 and n.329; Dkt. #2544-1/#2546-1 (Cantor Expert Rep.) at pp. 95-96 and Attachment 3 – Materials Considered at p. 8; **Ex. 30** [Purdue Exhibit list of September 10, 2019].

87 John Dombrowski, MD, and expert for distributor defendants McKesson Corporation, AmerisourceBergen Drug Corporation, and Cardinal Health included Mr. Hammergren's testimony in his report as material he considered in forming his opinions. *See* **Ex. 31** [Expert Report of John Dombrowski, MD, Exhibit C P. 3].

made. Evidence is not hearsay when it is not offered to prove the truth of the matter asserted. *See Anthony v. DeWitt,* 295 F.3d 554, 563 (6th Cir. 2002). "If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, and the statement is not hearsay." FED. R. EVID. 801, Advisory Committee Note to Subdivision (c), 1972 Proposed Rules. Further, "[s]tatements to prove the listener's knowledge are not hearsay." *U.S. v. Boyd,* 640 F.3d 657, 664 (6th Cir. 2011).

3. <u>McKesson MIL No. MCK-3</u>: The Court should prohibit the introduction of nationwide trends in drug deaths.

McKesson seeks to exclude certain Centers for Disease Control ("CDC") maps on the basis that Plaintiffs may inaccurately characterize the data depicted on the maps. But McKesson's expressed concerns do not warrant the remedy of exclusion of this evidence. If in fact McKesson believes that an inaccurate or misleading suggestion is made by Plaintiffs at trial regarding these maps, McKesson can object at the time and/or address the matter through cross-examination.

No more availing is McKesson's argument that the maps should be excluded as irrelevant because, in McKesson's view, Plaintiffs lack evidence that McKesson caused any death, and Plaintiffs may not "seek damages beyond their borders." Dkt. #2663-1 at p. 4. But these maps are relevant to numerous other issues, including by providing useful background with respect to the scope and nature of the opioid crisis, and showing (with appropriate qualification) the relationship between increased prescription opioid shipment and harms, including mortality—a subject of extensive expert testimony. As Plaintiffs' causation and damage experts make clear, increased shipments led to increased harms, and Plaintiffs' experts use mortality as the primary proxy for these harms – an analysis this Court has already blessed in rejecting Defendants prior complaints about the purported irrelevance of mortality in their *Daubert* motions. Indeed, as explained in Prof. Cutler's expert report, the field of health economics routinely studies how the use of substances—including addictive ones such as tobacco, alcohol, and more recently, opioids—are related to personal harms such as mortality. Dkt. #2000-4/#1999-4 (Cutler Expert Rep.) at ¶ 14. The use of mortality trends and statistics is hardly controversial, and in fact is of fundamental

relevance in measuring the magnitude of the harms caused by defendants' misconduct. Information of this type will greatly assist the jury in understanding the issues presented at trial.

Accordingly, McKesson's MIL No. MCK-3 should be denied.

4. McKesson MIL No. MCK-4: The Court should prohibit Plaintiffs from introducing evidence or argument about allegations contained in letters from the DEA or DOJ.

McKesson argues that allegations contained in enforcement letters from the DEA and DOJ should be excluded "[f]or substantially the same reasons that the Court should exclude settlement agreements." Dkt. #2663-1 at pp. 4-5. For the same reasons discussed in § B.1, *supra*, that evidence is not precluded by Rule 408 or any other rule of evidence. That evidence is relevant, among other reasons, to prove that McKesson engaged in intentional conduct, over many years and across the country, that was a substantial factor in causing the harm to Plaintiffs, and that they were on notice of the ways in which its conduct violated the law.

5. McKesson MIL No. MCK-5: The Court should prohibit introduction of testimony from McKesson witness Nathan Hartle because of Plaintiffs' badgering and abusive conduct.

McKesson improperly seeks to exclude the entirety of the 30(b)(6) testimony[88] from its designated witness Nathan Hartle based only on a couple of areas of questioning undertaken by Plaintiffs, which covered a small portion of a day long deposition that spanned nearly 400 pages of testimony. Dkt. #2663-1 at pp. 6-7. In reality, Plaintiffs' questioning of Mr. Hartle in his capacity as a 30(b)(6) witness was reasonable and tailored to the broad range of topics Mr. Hartle was designated to discuss. Mr. Hartle directly answered these questions and McKesson's belated

[88] Mr. Hartle was deposed in two different capacities in this case. On July 31, 2018, he testified as a 30(b)(6) designee. On August 1, 2018, he provided fact witness testimony as well. Given that McKesson's arguments in its motion *in limine* focus solely on Mr. Hartle's 30(b)(6) testimony, Plaintiffs respond only to the baseless accusations made as to that testimony. While there is equally no basis to exclude Mr. Hartle's fact testimony, Plaintiffs reserve the right to separately oppose exclusion of that testimony should that remedy be sought by McKesson in the future.

attempts to unpack that credible and admissible testimony should not be rewarded. Thus, McKesson's MIL should be denied in its entirety.[89]

First, McKesson's complete failure to seek assistance from the Special Master or the Court at or following Mr. Hartle's deposition demonstrates that Plaintiffs did not act in a "wasteful" and "abusive" manner as McKesson now contends. Dkt. #2663-1 at p. 6. Rather, McKesson's motion is nothing more than an improper attempt to exclude admissible testimony that is simply contrary to the liability picture it now intends to portray to the Court and the jury. Routinely throughout the discovery phase of this case Special Master Cohen was heavily involved in the conduct of depositions, and in fact, actually attending some of the depositions that were taken. Despite the Special Master's active involvement in the deposition process, McKesson never once asked for relief from the Special Master related to Mr. Hartle's deposition. This is telling, given that Mr. Hartle's 30(b)(6) deposition was only the third of twenty depositions taken of current or former McKesson employees during the discovery phase. If McKesson truly believed Plaintiffs acted in an abusive and wasteful fashion during Mr. Hartle's 30(b)(6) deposition it surely would have sought relief from the Special Master and/or the Court before Plaintiffs continued with seventeen additional depositions of McKesson witnesses, including the fact witness deposition of Mr. Hartle himself.

Second, the questioning addressed by McKesson was completely legitimate and consistent with the subject matter areas for which McKesson designated Mr. Hartle. McKesson designated Mr. Hartle on ten different topics that spanned broad areas concerning McKesson's duties under the CSA, the company's efforts to comply with the CSA, data concerning opioid orders supplied to CT1 pharmacies, and information concerning suspicious orders identified for CT1 pharmacies.[90]

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89 Although its criticisms of Mr. Hartle's deposition have no merit, McKesson could easily avoid having his deposition played at trial by simply making him available to testify live.

90 Specifically, Mr. Hartle was designated to cover the entirety of Plaintiffs' first 30(b)(6) notice and topics 9, 14, and 16-22 of Plaintiffs' second 30(b)(6) notice. *See* Dkt. #2663-4 (Amended First Notice of Deposition); Dkt. #2663-5 (Amended Second Notice of Deposition).

The testimony cited by McKesson concerning opioids being a gateway to heroin use certainly relates to McKesson's duties under the CSA and why those duties are important. McKesson concedes the relatedness of this inquiry, but instead complains that answering this question requires "specialized medical and public health knowledge." Dkt. #2663-1 at p. 6. As an expert in controlled substances generally, and opioids specifically, McKesson should have such specialized knowledge to be able to answer questions on this topic. Thus, McKesson alone had the ability and responsibility to select the appropriate person to address this inquiry. Moreover, Mr. Hartle had no problem answering the question posed of him on this subject because, in fact, he does possess such specialized knowledge himself.[91] Mr. Hartle has presented data on opioids being a gateway to heroin use to various McKesson pharmacy customers and to McKesson employees in his capacity as Senior Regulatory Affairs Director at McKesson.[92] The fact that McKesson trusted Mr. Hartle's expertise to discuss opioids being a gateway to heroin use in presentations to its own customers and its own employees alone completely undercuts the validity of McKesson's argument that Mr. Hartle lacks the requisite knowledge on this subject now.

Similarly, Mr. Hartle readily acknowledged, as the company's 30(b)(6) designee, McKesson's role in contributing to the opioid epidemic.[93] Given that Mr. Hartle was designated by McKesson to broadly speak to the company's compliance, or lack thereof, with its regulatory and societal responsibilities concerning opioid distribution, this testimony is well within the scope of topics Mr. Hartle could reasonably be expected to discuss. Moreover, McKesson is undoubtedly in an excellent position to judge its own culpability in contributing to the opioid epidemic, and as the company's designated spokesperson on those topics, Mr. Hartle is precisely the person that should be expected to answer this central question. *See* e.g., *Hilton Hotels Corp. v. Dunnet,* No. 00–2852–GV, 2002 WL 1482543, *2 (W.D.Tenn. Mar. 15, 2002) (30(b)(6) deponents are expected to speak as to

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91 Dkt. #1962-23/#1978-3 (7/31/18 Hartle Dep.) at 320:14-321:13.

92 *See* **Ex. 32** [MCKMDL00430424] at 425; **Ex. 33** [MCKMDL00448596] at 611; Dkt. #1962-24/#1978-4 (8/1/18 Hartle Dep.) at 34:16 – 40:3.

93 Dkt. #1962-23/#1978-3 (7/31/18 Hartle Dep.) at 285:6-286:15.

"the knowledge of the corporation and the corporation's subjective beliefs and opinions and interpretation of documents and events"). While McKesson no doubt dislikes the testimony Mr. Hartle offered on this point, that distaste does not justify the exclusion of this vitally important testimony.

Third, despite the fact that Plaintiffs' examination was tailored to the confines of the 30(b)(6) notices, Plaintiffs were not necessarily limited to questioning Mr. Hartle on matters specifically included in those notices. As outlined in *King v. Pratt & Whitney, a Div. of United Technologies Corp.,* 161 F.R.D. 475, 476 (S.D. Fla. 1995):

> Rule 30(b)(6) should not be read to confer some special privilege on a corporate deponent responding to this type of notice. … Rather, the Rule is best read as follows:
>
> 1) Rule 30(b)(6) obligates the responding corporation to provide a witness who can answer questions regarding the subject matter listed in the notice.
>
> 2) If the designated deponent cannot answer those questions, then the corporation has failed to comply with its Rule 30(b)(6) obligations and may be subject to sanctions, etc. The corporation has an affirmative duty to produce a representative who can answer questions that are both within the scope of the matters described in the notice and are "known or reasonably available" to the corporation. Rule 30(b)(6) delineates this affirmative duty.
>
> 3) If the examining party asks questions outside the scope of the matters described in the notice, the general deposition rules govern (i.e. Fed.R.Civ.P. 26(b)(1)), so that relevant questions may be asked and no special protection is conferred on a deponent by virtue of the fact that the deposition was noticed under 30(b)(6).
>
> 4) However, if the deponent does not know the answer to questions outside the scope of the matters described in the notice, then that is the examining party's problem.

This interpretation of the scope of examinations under Rule 30(b)(6) has been explicitly followed by courts in the Sixth Circuit. *See e.g., Harris v. Goins*, No. 6: 15-151-DCR, 2017 WL 4080692, *2 (E.D. Ky. Sep. 14, 2017) (citing *King*, 161 F.R.D. 475) ("Rule 30(b)(6) does not limit what can be asked at a deposition"). Thus, McKesson's contention that Plaintiffs somehow strayed from the 30(b)(6) topics is immaterial, as the notices themselves did not serve to limit the topical areas that could be addressed with Mr. Hartle.

Finally, even assuming the portions of the examination pinpointed by McKesson were improper – which they were not – McKesson has offered no justification or authority for excluding the entirety of Mr. Hartle's 30(b)(6) testimony based on the narrow set of issues it has identified. The glaring lack of authoritative support for this remedy speaks volumes to the futility of the motion itself. In fact, the more appropriate approach would be to deal with these issues through the process already in place to deal with objections to deposition designations. Wholesale exclusion of the entirety of Mr. Hartle's 30(b)(6) testimony is simply not the appropriate answer under any circumstances. McKesson's MIL No. MCK-5 should be denied.

6. <u>McKesson MIL No. MCK-6</u>: The Court should prohibit introduction of documents related to McKesson's relationship with CVA and Rite Aid in light of severance.

McKesson asks the Court to prohibit introduction of documents related to McKesson's relationship with CVS and Rite Aid because CVS and Rite Aid were severed from the Track I Trial. The Court should deny this MIL because: (1) evidence about McKesson's "relationship" with CVS and Rite Aid is central to Plaintiffs' civil conspiracy claim, so that evidence poses no danger of a "trial within a trial" – it is the trial itself; and (2) severance of defendants is not a basis for excluding any evidence about those defendants in a conspiracy case.

A critical component of Plaintiffs' conspiracy claim is the many actions and inactions by Distributor Defendants, including McKesson, to ensure that they and their pharmacy customers, including CVS and Rite Aid, could avoid having to report suspicious orders.[94] Far from creating a "trial within a trial," evidence about McKesson's relationship with CVS (McKesson's largest customer from 2008-2018) and Rite Aid goes directly to Plaintiffs' allegations that Distributor and Pharmacy Defendants conspired to protect and grow the opioids market by, inter alia, avoiding their reporting obligations to the DEA. One of the key provisions of McKesson's Controlled Substance Monitoring Program was creation of appropriate thresholds for opioid sales to pharmacy

[94] *See, e.g.*, Dkt. #2182 (Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment of Plaintiffs' Civil Conspiracy, RICO and OCPA Claims) at pp. 68-70.

customers.[95] Yet, McKesson repeatedly and automatically increased thresholds for both CVS and Rite Aid, without adequate due diligence, and failed to investigate or report suspicious orders by these chain pharmacies in order to advance their common purpose to avoid suspicious order reporting.[96] Such evidence does not pose any risk of a "trial within a trial" – it is evidence that will support Plaintiffs' conspiracy claim.[97] This evidence will not cause McKesson to defend CVS and Rite Aid's internal SOM processes, but its role in abdicating its own duties,[98] which again is evidence going directly to Plaintiffs' claims.

Second, McKesson cites no authority for the proposition that a defendant's severance precludes introduction of evidence regarding the relationship between that defendant and a non-severed defendant. Even assuming such a rule exists (which it does not), its application here would improperly hamstring Plaintiffs in presenting their conspiracy claim. Granting this motion would unduly prejudice Plaintiffs by preventing them from presenting direct evidence of McKesson's role in the conspiracy. Indeed, McKesson acknowledged that evidence regarding the relationship between Distributor Defendants and Pharmacy Defendants would be central to Plaintiffs' conspiracy claims when opposing severance. Dkt. #2143 at pp. 6-7. Under these circumstances McKesson's MIL No. MCK-6 should be denied.

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95 Dkt. #1959-4 (1/17/19 Boggs Dep.) at 88:19–89:18.

96 *See, e.g.*, Dkt. #1971-19 (1/10/19 D. Walker Dep.) at 279:4-24, 288:6–291:1; Dkt. #2261-10 (MCKMDL00632825); Dkt. #2261-26 (MCKMDL00627723); Dkt. #2261-25 (MCKMDL00629858); Dkt. #2261-28/#2371-86 (MCKMDL00632923); Dkt. #2261-27 (MCKMDL00646634).

97 The cases McKesson cites do not support exclusion of evidence in this trial of McKesson's involvement with other actors as part of a conspiracy. *Chism v. CNH Am., LLC*, 638 F.3d 637, 642 (8th Cir. 2011) (in personal injury case against manufacturer of hay baler, excluding evidence of other accidents involving hay balers because of lack of substantial similarity); *Widmer v. Warden, Corr. Reception Ctr.*, 2017 WL 447237, at *49 (S.D. Ohio Feb. 2, 2017) (in habeas corpus action seeking relief from murder conviction, refusing to allow inmate to cross-examine investigator based on alleged prior instance of untruthful conduct where authenticity of document on which request was based was questionable). In both instances, evidence was excluded for other reasons besides the "trial within a trial" rationale. More importantly, in neither instance was the evidence sought to be excluded directly relevant to the plaintiff's claim, like the evidence McKesson seeks to exclude here.

98 Dkt. #2169-32/#2713-50 (7/19/18 Oriente Dep.) at 548:22-550:1.

G. PLAINTIFFS' RESPONSE TO TEVA DEFENDANTS' AND ACTAVIS GENERIC DEFENDANTS' OMNIBUS MOTION IN LIMINE (DKT. #2668).

1. Teva MIL No. TAD-1: The Court should exclude reference to the Cephalon misdemeanor plea.

Moving Defendants[99] seek to exclude evidence regarding a criminal plea agreement entered into by one of their related companies, Cephalon. The motion attempts to minimize the severity of the criminal activity, describing it as "a single misdemeanor count of off-label promotion of three medicines, only one of which was an opioid) limited to an eight-month period in 2001." Dkt. #2668-1 at p. 1. The reality is far more serious. The opioid drug in question was Actiq, which was approved by the FDA in 1998 solely for the management of "breakthrough pain" in opioid-tolerant cancer patients. The FDA restricted its use because Actiq was a powerful narcotic – fentanyl – in the form of a fast-dissolving lollipop, also known as a Transmucosal Immediate-Release Fentanyl product (TIRF).

In 2000, Actiq generated a relatively modest $16 million in revenue for its then-owner Anesta. That same year Cephalon purchased Anesta. Cephalon set extremely high sales goals for Actiq, pressuring employees to generate volume sales. The pressure tactics worked spectacularly well. By 2006, Cephalon's Actiq sales were $590.7 million, more than 36 times the amount sold in 2000. The massive increase in sales was driven largely by fraudulent marketing – criminal acts that were later admitted by Cephalon. The "single misdemeanor count of off-label promotion" resulted in $425 million in fines and settlements. Cephalon and its successors were also required to adhere to a five-year "Corporate Integrity Agreement" governing marketing practices. The evidence supporting these facts was included in Plaintiffs' Opposition to Teva/Actavis' Motion for Summary Judgment. Dkt. #2220 at pp. 5-6.

For the same reasons discussed in § B.1, *supra*, this evidence is relevant and admissible, and not properly excluded under Rule 403. It is relevant, among other reasons, to prove that Moving

[99] "Moving Defendants" are the Teva Defendants and the Actavis Generic Defendants, as defined in their motion *in limine*. Dkt. #2668-1 at p. 1 & n.1.

Defendants engaged in intentional conduct, over many years and across the country, that was a substantial factor in causing the harm to Plaintiffs.

Moving Defendants argue the Cephalon plea is inadmissible character evidence, but they are wrong. If they were being prosecuted for off-label promotion of a different drug, or at a later time, and the government sought to prove their guilt by introducing evidence of this prior conviction, that evidence would likely be barred by Rule 404. But that is not the purpose for which the evidence will be offered here. Rather, as Rule 404(b) notes, character evidence "may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." FED. R. EVID. 404(b)(2). In this case, these Defendants' intent is an element of Plaintiffs' claims, and their ongoing and repetitive conduct improperly and falsely promoting the use of dangerous opioid medications is central to those claims. Accordingly, Moving Defendants MIL No. TAD-1 should be denied.

2. <u>Teva MIL No. TAD-2</u>: The Court should exclude reference to "off-label" promotion.

Moving Defendants' MIL No. TAD-2 seeks to preclude Plaintiffs from offering any testimony, evidence, or argument that Cephalon, Teva USA, or any other Moving Defendant's conduct constituted off-label promotion. Dkt. #2668-1 at pp. 4-6. Moving Defendants assert that any reference to off-label promotion is irrelevant and would confuse the jury. Both of these arguments should be rejected as red herrings.

Moving Defendants argue that evidence and testimony about off-label promotion is irrelevant be-cause promoting the off-label use of drugs is not inherently false or misleading. *Id.* at p. 4. But even if misleading messaging were not part of Moving Defendants' off-label promotion, false marketing is not the only basis for Plaintiffs' claims. Evidence regarding off-label promotion is relevant to Plaintiffs' argument that the massive overpromotion of opioid use led to the creation of the public health crisis confronting their communities. Evidence or testimony that Actiq and Fentora, for example, were promoted for noncancer pain caused by migraines and injuries when they were only approved for cancer pain in opioid-tolerant patients is relevant to the argument that

excessive promotion of opioids created a public health crisis. Aggressive overpromotion of dangerous drugs need not be fraudulent to be unlawful. Evidence regarding Moving Defendants' promotion of their opioids for a multitude of uses beyond those approved is fundamentally relevant to Plaintiffs' claims in this case. *See* Dkt. #2000-8 (Kessler Expert Rep.).

Moving Defendants also argue that FDA regulations are "arcane," *id.* at p. 5, and "risk sucking the jury down an irrelevant rabbit hole of confusion and side issues." *Id.* at p. 4. But the jury is not tasked with determining whether Moving Defendants' conduct violated FDA regulations surrounding off-label promotion or whether certain communications were protected speech, and it need not do so in order to determine whether Defendants' conduct substantially contributed to the opioid epidemic. Moving Defendants raise the specter of "an irrelevant, confusing and highly prejudicial mini-trial," but the jury need not "assess[] whether Defendants' conduct constituted off-label activity[.]" *Id.* at pp. 5-6. The question is whether Moving Defendants' conduct in aggressively over-promoting their opioid products (whether for approved or off-label uses) was a substantial factor in causing the harms caused by overprescribing alleged by Plaintiffs. Answering this question does not require determining whether Defendants' off-label promotion complied with FDA regulations. Evidence, testimony, and argument regarding Moving Defendants' promotion of drugs for uses beyond the approved indications are relevant and should not be excluded.

3. <u>Teva MIL No. TAD-3</u>: The Court should exclude any reference to the 2008 civil settlement between Cephalon and the Federal Government.

The arguments asserted by Moving Defendants in their MIL No. TAD-3 are addressed in § B.1, *supra*. Rule 408 does not preclude this evidence, and it is both relevant and not unfairly prejudicial.

4. <u>Teva MIL No. TAD-4</u>: The Court should exclude evidence of opioid-related harm that occurred outside of the counties.

Moving Defendants seek to prohibit any evidence regarding harm that occurred outside of Ohio, on the theory that the Plaintiffs can only recover for harm that they incurred. As initial matter, it is unclear what Moving Defendants mean by "evidence of harm," and hence exactly what

evidence Moving Defendants are seeking to exclude. To the degree that Moving Defendants have specific evidence in mind, and that they are simply choosing not to identify it at this time, the appropriate course is for them to object when that evidence is offered at trial, as opposed to seeking an unspecified adjudication in a vacuum.

But more importantly, the fact that Plaintiffs cannot recover for harm incurred outside Ohio does not mean that the impact of Defendants misconduct outside of Ohio is irrelevant or should be ignored. Moving Defendants reference, by way of example, national studies on opioid abuse relied on by Plaintiffs' experts. Dkt. #2668-1 at p. 9. These studies are relevant to numerous issues, including providing the context and background with respect to the scope and nature of the opioid crisis. This is a crisis which many Defendants are disputing actually exists. Further, evidence of the national scope and nature of the crisis will be pertinent to any attempt by Defendants to blame the Plaintiffs for the harms by suggesting bellwether-specific failures are the cause of the harms. Indeed, the Court has already rejected Defendants' arguments seeking to exclude Plaintiffs' causation and damage experts who analyze national and aggregate trends to create their models. As Plaintiffs' expert reports make clear, and explained by Plaintiffs in their opposition briefs to Defendants' *Daubert* motions, national trends and statistics make Plaintiffs' analyses more reliable and relevant, and strengthen the reliability of the relationship between increased shipments of prescription opioids and increased harms. *See, e.g.,* Dkt. #2000-4/#1999-4 (Cutler Expert Rep.) at ¶¶ 81-100 (explaining the most appropriate way to assess the relationship between shipments and mortality is based on regression-based comparisons across a robust sample of counties across the nation, not just one or two counties viewed in isolation); *see also* Dkt. #2000-6/#1999-6 (Gruber Expert Rep.) at ¶ 84, Fig. 1.18 (showing that in counties with the highest per capita shipments between 1997 and 2010, the prescription opioid mortality rate increased over 3.75 times more than it did in the counties with the lowest per capita shipments); *see also Royal Park Investments SA/NV v. U.S. Bank Nat'l Ass'n*, 2017 WL 4748054, at *3 (S.D.N.Y. Oct. 19, 2017), *aff'd*, 349 F. Supp. 3d 298 (S.D.N.Y. 2018) ("[I]t seems axiomatic that the more data points that are available, the more reliable the ultimate damage calculation"). As such, information on the opioid crisis and its national scope is directly relevant to

both claims and defenses at issue in the litigation, and will greatly assist the jury in understanding the issues presented at trial. *See also supra* at § A.6.

5. <u>Teva MIL No. TAD-5</u>: The Court should exclude evidence of marketing-related statements or opioid shipments outside of the counties.

Moving Defendants also seek to exclude "evidence of marketing activity" where there is no showing that the marketing materials were distributed, published, or read in either County, as well as any evidence of shipments of opioids manufactured by Defendants that have no connection to Ohio. Moving Defendants' arguments regarding shipments outside of Ohio are addressed in Plaintiffs' response to Defendants' Omnibus MIL No. 6. *Supra* at § A.6. With respect to Moving Defendants' marketing arguments, the factual premise underpinning these arguments is false. The evidence in the record demonstrates that both Teva and Actavis engaged in nationwide marketing. There was no state-specific marketing, including state-specific marketing in Ohio, and any national marketing would have been used in all 50 states. *See, e.g.,* Dkt. #1962-26/#1978-06 (11/16/18 Hassler Dep.) at 275:12 – 276:17 (confirming that for Teva, Cephalon and Actavis, marketing, sales and advertising pieces were national in scope, in that "they are able to be used all over America," and that these materials were not tracked, such that defendants have no way showing that such materials were not used in Ohio); **Ex. 34** [Hassler Dep. Vol II] at 621:10-19 (testifying that Teva and Cephalon did not release materials that were specific to geographic areas for their marketing or educational messages, and that "[t]he messages were approved nationwide, and they would have been available and used in Ohio, just as they would have been in any other state in the country."); Dkt. #2177-5 (11/2/18 Snyder Dep.) at 271:5 – 272:3 (testifying that Kadian marketing materials were national in that the same marketing materials were provided and used by sales reps across the country).

Finally, Moving Defendants' constitutional argument—that it is unconstitutional to "project Ohio's regulatory regime into another state"—is simply misplaced. Dkt. #2668-1 at pp. 10-11. Plaintiffs are not seeking to project Ohio's regulatory regime into another state, nor are they seeking to "penalize" Moving Defendants for conduct outside of Ohio. Defendants' misconduct violated

not only Ohio law, but also federal law and the local laws of any non-Ohio jurisdiction within which the conduct occurred. As Plaintiffs will demonstrate at trial, the evidence in the record establishes that Moving Defendants have engaged in misconduct, and caused significant injury, within Plaintiffs' jurisdictions. But Plaintiffs are also entitled to introduce evidence showing the systemic nature of Moving Defendants' misconduct, and the degree to which this conduct caused a national opioid crisis that impacted the bellwether jurisdictions.

6. Teva MIL No. TAD-6: The Court should exclude evidence regarding Teva Defendants' financial support of third-party groups.

Moving Defendants claim Plaintiffs should be precluded from offering evidence or argument of their funding of third-party trade groups because such conduct is protected by the First Amendment's right to freedom of association.[100] Not so. Plaintiffs are not arguing that Moving Defendants' mere participation in, and funding of, various trade and advocacy organizations, in and of themselves, subject them to liability. Rather, Plaintiffs allege, and will demonstrate at trial, that Moving Defendants worked together, through their trade associations and otherwise, (i) to unlawfully deceive and mislead the public, the medical community, and the government regarding the risks of their opioids and their purported efforts to prevent diversion, and (ii) to unlawfully avoid their legal duties to monitor for, report, and prevent shipment of suspicious orders of opioids. Evidence of Moving Defendants' participation and funding of these trade associations is relevant to demonstrate that they participated in this conspiracy with the intention of furthering this wrongful conduct. *See In re Welding Fume Products Liab. Litig.*, 526 F. Supp. 2d 775, 803 (N.D. Ohio 2007)

[100] In their motion, Moving Defendants quote the following language from the Supreme Court: " 'The freedom to associate with others for the dissemination of ideas—not just by singing or speaking in unison, but by pooling financial resources for expressive purposes—is part of the freedom of speech.' " Dkt. #2668-1 at pp. 11-12 (quoting *McConnell v. Fed. Election Commn.*, 540 U.S. 93, 255 (2003), *overruled on other grounds by Citizens United v. Fed. Election Commn.*, 558 U.S. 310 (2010)). They fail to mention this language was taken from Justice Scalia's *dissent* in that case. *McConnell*, 540 U.S. at 247-48, 255. (In *McConnell*, Justice Scalia concurred in part and dissented in part, but the quoted language is in a section of his opinion in which he is criticizing the majority opinion. *Id.* at 250, 255-56.).

("*Welding Fume I*") (recognizing that there are circumstances in which "joint activity undertaken through a trade association" can be "evidence of a conspiracy").[101]

Moving Defendants also claim that Plaintiffs should be precluded from arguing that they are responsible for statements made by these third-party groups because Plaintiffs have not and cannot demonstrate that any third-party group was acting as their agent. Dkt. #2668-1 at p. 12. This Court already rejected this argument in its opinion denying the Teva Defendants' summary judgment motion:

> The Court rejects the Teva Defendants' argument that Plaintiffs cannot show an agency relationship existed between the Teva Defendants and the third parties they "partially" funded. In the "Pain Matters" presentation, Gudin told the audience: "this program was developed by Teva Pharmaceuticals, . . . the three of us are presenting on behalf of Teva, and . . . we've been compensated by Teva to give this presentation." Clearly, material fact issues exist in this regard.

Dkt. #2564 at pp. 3-4 n.5 (internal citations omitted). *See also* Dkt. #2565 at p. 19 ("Whether groups like APF were truly independent third parties or merely front groups, remains an issue of fact for the jury. Though Teva contends that funding to these third-party organizations was conditional on their independence, it is the jury's province to decide whether third-party agreements requiring independent were actually followed; and this, to large extent, may depend on the credibility of the witnesses called. . . . A reasonable finder of fact could conclude . . . that the Teva entities directly, as well as through front groups and CME programs, falsely represented the risk of opioid addiction, and that these representations were not tied to specific brand names, but applied to opioids generally.") (internal citation omitted).[102]

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[101] *See also AirCo, Inc.*, 2003 WL 27382684, at *16 (rejecting defendants' argument that dismissal of plaintiff's civil conspiracy claim was warranted because members of a trade association cannot be held liable "for simply exercising their first amendment rights by attending meetings[,]" because the complaint did "not seek to hold Defendants responsible merely for attending trade association or scientific meetings[,]" but rather "allege[d], beyond mere membership, that they . . . took specific affirmative acts at meetings in which specifically-named entities agreed to perpetrate a series of frauds").

[102] Thus, Plaintiffs have already made an evidentiary proffer that the Court considered sufficient to withstand summary judgment.

The cases cited by Moving Defendants, none of which involved motions *in limine*, are factually inapposite. *See Gen. Bldg. Contractors Ass'n, Inc. v. Pennsylvania*, 458 U.S. 375, 395 (1982) (in a § 1981 racial discrimination action, defendants could not be held vicariously liable, under *respondeat superior*, for the discriminatory conduct of third party where there was no evidence in the record that the third party was acting as the defendants' agent; "That the employers fund the activities of the JATC does not render the JATC the employers' servant or agent any more than an independent contractor is rendered an agent simply because he is compensated by the principal for his services. The employers must also enjoy a right to control the activities of the JATC, and there is no record basis for believing that to be the case."); *Natl. Ass'n for Advancement of Colored People v. State of Ala. ex rel. Patterson*, 357 U.S. 449, 451 (1958) (addressing whether the state of Alabama could compel the NAACP "to reveal to the State's Attorney General the names and addresses of all its Alabama members and agents, without regard to their positions or functions in the Association"); *McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008) (plaintiff failed to allege "any agency relationship between the pilot and the aircraft owner[,]" and therefore could "not impute [the pilot's] alleged negligence to [the owner]"; bare allegation in complaint that "[a]ll acts of [the aircraft owner] were done by its agents" was "insufficient to establish agency");[103] *Welding Fume I*, 526 F. Supp. 2d at 803 ("There is no evidence that would allow a jury to conclude that Caterpillar actually joined any conspiracy by agreeing to cooperate with other defendants, intending to help them achieve the objective of hiding the hazards of manganese in welding fume. This is so because, from the beginning, Caterpillar's actions and statements reveal that, in most regards, it was actually working at cross-purposes from the supposed objectives of the conspiracy."); *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416-18 (S.D. Ohio 1986) (holding franchisor had sufficient right of control over

[103] In their motion, Moving Defendants describe *McWilliams* as holding a "defendant not liable for third-party statements because [there was] no evidence that [the] third party acted as defendant's agent with respect to the challenged statements[.]" Dkt. #2668-1 at p. 13 n.11. But that case does not address liability for third-party statements. Rather, the issue was whether the owner of a skydiving plane owed a duty to the skydiver "to inspect the harness or ensure its safety" based on the owner's relationship with the pilot. 581 F. Supp.2d at 893. The court held that the pilot's negligence could not be imputed to the owner because the plaintiff had failed to allege an agency relationship between the two. *Id.*

franchisee check collection company under their contract to make franchisee its "agent" in regard to franchisee's acts giving rise to check drawer's action against franchisor for liability under the Fair Credit Reporting Act and the Fair Debt Collection Practices Act); *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017) ("Of course, *alone*, membership in a trade organization like CANAERO does not make Defendants part of an enterprise.") (emphasis added); *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1290-94 (3d Cir. 1994) (former manufacturer of asbestos products could not be held civilly liable for any wrongful conduct committed by [the trade association] SBA or its members in the years after SBA's formation unless it can be shown that [the manufacturer's] actions taken in relation to the SBA were specifically intended to further such wrongful conduct" and "[h]ere, there is simply no evidence that [the manufacturer] had such an intent"; critically, the court noted that there was no evidence that the manufacturer "had 'tacitly or overtly agreed' with the other defendants to continue selling its product without warnings or had been a party to 'written agreements, meetings, and other communications among asbestos defendants to conceal their knowledge of the dangers of asbestos from the public' ").

For these reasons, Moving Defendants' MIL No. TAD-6 should be denied.

7. <u>Teva MIL No. TAD-7</u>: The Court should exclude testimony from Russell Portenoy about any improper conduct by Moving Defendants.

Moving Defendants' MIL No. TAD-7 is an improper attempt to evade possibly adverse relevant testimony by a witness whom the Court expressly permitted Teva to depose, but Teva declined to do so. Moving Defendants argue that Plaintiffs should be precluded from eliciting testimony from witness Dr. Russell Portenoy about any improper conduct by Teva because he allegedly testified in the State of Oklahoma prescription opioid litigation that he was unaware of any such conduct. Dkt. #2668-1 at 13-14. The Court should reject this argument as procedurally improper.

Moving Defendants have not demonstrated that Dr. Portenoy's trial testimony here would contradict his prior testimony in the Oklahoma case. Even assuming it did, the remedy would not be exclusion under FED. R. EVID. 402, as Moving Defendants aver, *see* Dkt. #2668-1, but

impeachment under FED. R. EVID. 613(b). *See*, *e.g.*, *United States v. Foster*, 376 F.3d 577, 591 (6th Cir. 2004) ("Glover's prior inconsistent statement is admissible under Federal Rule of Evidence 613(b), which permits the impeachment of a witness . . . ."). Since Moving Defendants may try to impeach Dr. Portenoy using any allegedly contrary prior testimony, the Court should reject this motion to preemptively limit his trial testimony here.

An *in limine* ruling would be particularly inappropriate here because the Court issued an Order expressly permitting Teva and all Defendants to depose Dr. Portenoy. Dkt. #1577 (Order re Discovery Order No. 19) at p. 8 ("[T]he Court concludes that a more appropriate sanction is to allow Defendants to take Dr. Portenoy's deposition at Plaintiffs' counsel's expense. Further, should Defendants deem it necessary, the Court will consider, on a motion by Defendants, allowing a small amount of supplemental discovery and deposition testimony from additional fact witnesses that Defendants sincerely believe could 'challenge Dr. Portenoy's specific claims about Defendants' supposedly misleading marketing. . . ."). The Court placed no substantive limits on Defendants' deposition of Dr. Portenoy, thus permitting Moving Defendants to probe the full range of his factual knowledge and also to obtain additional rebuttal evidence as needed.

Moving Defendants chose not to do so. At one point, Defendants expressed an intent to exercise their right to depose Dr. Portenoy. A dispute then arose concerning the scope of his deposition, particularly over whether questioning would or would not be limited to the scope of his Oklahoma testimony and over whether Plaintiffs, too, would be permitted to question him. Special Master Cohen ruled in a telephonic hearing that questioning of Dr. Portenoy *would not* be limited to the scope of his Oklahoma testimony, which he found to be "incomplete," and that *all parties* including Plaintiffs would be permitted to question him. *See* **Ex. 35** [Transcript of July 18, 2019 Teleconference with Special Master Cohen re Dr. Portenoy Deposition]. After the Special Master so ruled, Teva and its co-Defendants backpedaled and chose to decline the Court's invitation to depose Dr. Portenoy. Having done so, Moving Defendants may not now obtain an order precluding allegedly inconsistent testimony that they could have fully probed and rebutted through discovery and may still try to impeach at trial.

For all of these reasons, the Court should deny Moving Defendants' MIL No. TAD-7 concerning Dr. Portenoy.

8. Teva MIL No. TAD-8: Plaintiffs should be precluded from arguing that the Actavis Generic Defendants should have made additional warnings regarding their generic medicines or should have stopped selling them.

Moving Defendants' joint motion to preclude argument that the Actavis Generic Defendants should have made additional warnings regarding generic opioids is an improper attempt to re-litigate the preemption theory Defendants already lost. Dkt. #2565 (Opinion and Order Re: Preemption) ("Preemption Order"). In the Preemption Order, the Court summarized Plaintiffs' theory that "*all* manufacturers engaged in the false marketing of opioids generally, frequently through unbranded promotion." Dkt. #2565 at p. 12 (emphasis in original). "[A]ny distinction . . . between those defendants who manufactured brand name opioids, those who manufactured generic opioids, or, as appears to be most common, those who manufactured both, would be rendered largely immaterial." *Id.* As the Court found, because "Plaintiffs' state law claims are *not* predicated upon violations of the FDA or CSA, nor are they accurately characterized as 'fraud on the FDA' or 'fraud on the DEA' claims," preemption simply does not apply. Dkt. #2565 at p. 10 (emphasis in original).

Moving Defendants' reliance on *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 5258858 (S.D. Ohio Sept. 10, 2015), is inapt. Dkt. #2668-1 at p. 15. In *Rheinfrank*, the Court granted a motion *in limine* on plaintiff's failure to warn claim because the FDA had affirmatively found the warning at issue "'should not be incorporated'" into defendant's drug label. 2015 WL 5258858 at *2 (citation omitted). No parallel exists here.

Moving Defendants also argue they had no duty to "correct[] alleged impressions *by others* about opioids." Dkt. #2668-1 at p. 15 (emphasis added). But that straw man does not address Plaintiffs' claim; Plaintiffs allege that Teva/Actavis engaged in affirmative misrepresentations in their branded and unbranded marketing, and failed to correct their *own* representations, not others'.

Second, Actavis Generic Defendants' employees, including some that designated to testify at trial here, were active participants on the boards that conducted non-branded marketing.[104] As such, Plaintiffs have put forward evidence sufficient to show that the Actavis Generic Defendants themselves "engaged in the false marketing of opioids generally, frequently through unbranded promotion." Dkt. #2565 at p. 12. Such promotional activities are not preempted. *Id.* at p. 10; *see also* Dkt. #1499, *The Muscogee (Creek) Nation v. Purdue Pharma L.P.*, Report and Recommendation re: Motion to Dismiss, at p. 35 n.29 (denying motion to dismiss marketing claims because "some of the Generic Manufacturers or their corporate affiliates are also alleged to sell name-brand prescription opioids"). Plaintiffs have never advanced any argument that Moving Defendants needed to "stop selling" opioids (Dkt. #2668-1 at p. 15), just that they could not do so with false and misleading marketing.

For these reasons, Moving Defendants' MIL No. TAD-8 should be denied.

9. <u>Teva MIL No. TAD-9</u>: The Court should exclude reference to the purchase price paid by Teva Pharmaceutical Industries Ltd. for the Actavis Generic Defendants.

Moving Defendants move to exclude reference to the purchase price Teva Pharmaceutical Industries Ltd. paid for the Actavis Generic Defendants in 2016 on grounds that the price is irrelevant and unduly prejudicial. It is neither. The purchase price is relevant because it indicates that, as of 2016, the acquisition of the Actavis Generic Defendants and their portfolio of generic opioids was worth approximately $40.5 billion. Opioids were massively profitable for Defendants, due in substantial part to extensive marketing based on misrepresentations and the failure to comply with the CSA's SOM requirements. Teva's willingness to pay tens of billions dollars in order to acquire the rights to sell a large number of generic opioids, including oxycodone, oxymorphone, morphine sulfate, and fentanyl, is relevant to the jury's understanding of the value of and expectations for sales of generic opioids.

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[104] Dkt. #2383-1/#2290-1 at 391:22-393:5 (Michael Perfetto on NACDS planning board); Dkt. #2380-20/#2287-20 at 431:3-14 (Douglas Boothe on GPhRMA board).

Moving Defendants' reliance on *Brooks v. Caterpillar Glob. Mining Am. LLC*, No. 4:14-cv-00022-JHM, 2017 WL 3401476 (W.D. Ky. Aug. 8, 2017), is inapt. Dkt. #2668-1 at p. 16. The claim in that case concerned a design defect claim concerning a single accident sustained by a coal miner; as such, defendant's financial condition was properly found irrelevant. 2017 WL 3401476, at *1. This case, concerning decades of misrepresentations and failures to meet regulatory requirements, could not be more different. *Gonzalez Prod. Sys. Inc. v. Martinrea Int'l Inc.*, No. 13-cv-11544, 2015 WL 4934628 (E.D. Mich. Aug. 18, 2015), is more informative. There, the court denied in part defendant's motion *in limine* to exclude the financial condition of defendant because it determined that such evidence "pertain[ed] to [defendant's] knowledge and potential motives for [defendant's] actions." *Id.* at *11. Similarly, the amount paid by Teva to acquire the Actavis Generic Defendants is relevant and probative of how valuable generic opioids were viewed by a pharmaceutical company.

Nor is the purchase price unduly prejudicial. Moving Defendants posit a strawman fallacy, contending that Plaintiffs will use the purchase price to communicate Teva's "current financial health" to the jury. Dkt. #2668-1 at p. 17. Not so. In fact, the Teva entity that purchased the Actavis Generic Defendants – Teva Pharmaceutical Industries Ltd. – is not a defendant at the trial for which Moving Defendants seek exclusion of the sale price. Dkt. #2673. Contrary to *City of Cleveland v. Peter Kiewit Sons' Co.*, on which Moving Defendants rely (Dkt. #2668-1 at p.), references to the purchase price will *not* be "'clearly calculated to direct the jury's attention to . . . compensation rather than the real issues in the case.'" 624 F.2d 749, 756-57 (6th Cir. 1980). Rather, as set forth above, the purchase price is probative of the market value of a portfolio including generic opioids in 2016 – even after the role of prescription opioids in creating the opioid crisis was a matter of national discussion. The purchase price is, therefore, indicative of "the real issues in the case." It is not unduly prejudicial.

10. <u>Teva MIL No. TAD-10</u>: The Court should exclude reference to the settlement agreement between Teva Ltd. and Allergan.

Plaintiffs have no objection to Moving Defendants' MIL No. TAD-10.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny each of Defendants' joint and individual MILs, except as otherwise indicated above.

Dated: October 7, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing instrument was served via email to defense counsel and to Special Master Cohen on October 7, 2019.

s/Peter H. Weinberger
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *Track One Cases*	MDL NO. 2804 Civ. No. 1:17-md-02804-DAP HON. JUDGE DAN A. POLSTER

OMNIBUS REPLY IN SUPPORT OF DISTRIBUTOR DEFENDANTS' MOTIONS IN LIMINE

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I. INTRODUCTION

AmerisourceBergen, Cardinal Health, McKesson, and Henry Schein (collectively, "Distributors") hereby reply to Plaintiffs' responses to Distributors' Motions in Limine. As with their opposition to the omnibus Defendants' motions in limine, Plaintiffs' opposition (while long on pages) is short on substance and contains nothing that calls into question the correctness of the in limine rulings Distributors request.

II. REPLIES IN SUPPORT OF MOTIONS IN LIMINE

1. [D-1] The Court Should Preclude Plaintiffs from Offering Evidence of, or Arguments about, Distributors' Settlements with the DEA and West Virginia.

Distributors' motion seeks a ruling that precludes evidence and arguments about settlements with the DEA and West Virginia. In response, Plaintiffs say that, of course, a settlement may be admissible if it is offered for a purpose *other than to prove liability*. Opp. 54. But it is plain as day that Plaintiffs intend to offer the DEA and other settlements to prove liability because whenever Plaintiffs have cited the settlements—most notably in their Complaints and summary judgment motions—it has been as evidence that Defendants failed to implement effective systems to prevent diversion. Distributors' motion cited seven examples of this from Plaintiffs' summary judgment papers alone.[1] Thus, there is no mystery about Plaintiffs' purpose in discussing the settlement agreements, and Federal Rule of Evidence ("Rule") 408 forbids the use of settlements for that purpose.

[1] Distrib. MIL at 2 (citing Dkt. Nos. 1910-1 at 69–71, 81–82, 88, 93, 105–11, 113, 119–22). At these pages, Plaintiffs assert that Cardinal Health's 2012 DEA settlement "admitted that it failed to comply with the requirements of the CSA"; that McKesson's 2008 DEA settlement "Confirms the Lack of CSA Compliance"; that McKesson's 2017 DEA settlement "Admitted It Violated the Requirements of the CSA from 2009-2017"; that ABDC's 2007 DEA settlement was an agreement "to stop shipping suspicious orders in violation of the 'shipping duty'"; and that Walgreen's 2013 DEA settlement "admitted that it had failed to comply with its obligations under the CSA."

Plaintiffs argue that the DEA settlements were about "some other claims" than those at issue in this trial, and that Rule 408 therefore does not even apply. Opp. 53 (citing *Uforma/Shelby Bus. Forms, Inc. v. N.L.R.B.*, 11 F.3d 1284 (6th Cir. 1997).[2] Distributors agree that the settlements were about "some other claims," but that does not help Plaintiffs—instead, it underscores that the settlements are irrelevant and any reference to them would be based on a "if it happened there, it must be happening here" premise. Distrib. MIL at 4–5. As noted, Plaintiffs repeatedly cite the settlements as evidence that Defendants did not have compliant suspicious-order monitoring systems—the very claim in this case.[3]

Nor does Rule 406 provide a backdoor to admissibility. ***First***, the settlements do not establish that Distributors "engaged in 'systematic, particularized, and repetitive conduct' by selling prescription opioids without proper, effective controls to prevent diversion." Opp. 56. Settlements are not adjudications, and these settlement agreements did not contain factual findings. Three of the six settlements did not include admissions of any kind, and the other three contained narrow admissions that did not implicate distribution of opioids to Cuyahoga or Summit Counties. Distrib. MIL at 5. ***Second***, even if the settlements did "establish" facts, neither one settlement (in the case of ABDC and Walgreens) nor two (Cardinal Health and McKesson) over a period of 20 years reflects a "routine" practice.[4] And the settlements, which do not concern distributions to Cuyahoga and Summit Counties, certainly do not establish that

[2] The *Uforma/Shelby* decision (and the excerpt from Wright & Miller on which it relies) concerned a very different issue—whether Rule 408 protects a wrong committed in the course of the settlement discussions. Specifically, in *Uforma/Shelby*, the issue was whether evidence of management's threats of retaliation in the course of settlement discussions of a labor grievance could be used, apart from the grievance, to prove an unfair labor practice claim for retaliating against the union's filing of the grievance. 111 F.3d at 1293–94.

[3] As noted below, Plaintiffs' argument regarding the settlement agreements is internally inconsistent. If it is true, as Plaintiffs claim later in their opposition, that the settlements "*concern*[] *the same violations alleged here*," then Rule 408 plainly prohibits their admissibility.

[4] *See* Opp. 56 (noting that Cardinal Health's and McKesson's second DEA settlements were "roughly a decade later"). In the case of McKesson, moreover, its SOM system changed materially in the intervening decade, further undermining any assertion of a "pattern."

the particular conduct of any Distributor was routine practice as to either county.[5] ***Third***, Plaintiffs misunderstand the purpose of Rule 406, which is to use proof of routine practice to show what happened in a particular case. Thus, in the case cited by Plaintiffs, the defendant sought to prove that it gave the negligent driver its standard rental agreement by showing that it was a matter of routine practice to provide that document to rental customers. *Martin v. Thrifty Rent A Car*, 1998 WL 211786, at *5 (6th Cir. Apr. 23, 1998) (citation omitted). Here, by contrast, Plaintiffs have disclaimed any intention to prove that a particular prescription was medically unwarranted or that a particular pharmacy order was suspicious, electing to proceed with aggregate proof.

Plaintiffs' next argument—that the settlements are relevant—contradicts its initial arguments, Opp. 53–54, that Rule 408 does not apply because the settlements concern "some other claim" and are offered for a purpose other than to prove liability. Plaintiffs argue that the DEA settlements describe "investigations and findings … *concerning the same violations alleged here*." Opp. 57 (emphasis added).[6] And Plaintiffs misleadingly add that the agreements "apply to all (or at least most) distribution centers." Opp. 57–58 (citing only one McKesson and one ABDC settlement). But while the prospective aspects of the settlement agreements may in some instances have applied to all of the Distributor's distribution centers, the investigations that gave rise to the agreements did not concern all centers—and did not concern the centers that distributed to Cuyahoga and Summit Counties. Distrib. MIL at 5.

[5] The very case that Plaintiffs rely on makes clear that the Rule 406 inquiry "require[s] some comparison of the number of instances in which any such conduct occurs with the number in which no such conduct took place," and further instructs that "before a court may admit evidence of habit, the offering party must establish … more than a mere 'tendency' to act in a given manner, but rather, conduct that is 'semi-automatic' in nature." *Bell v. Consol. Rail Corp.*, 299 F. Supp. 2d 795, 800 (N.D. Ohio 2004). For that very reason, the *Bell* court excluded generalized evidence that the defendant routinely provided locomotives with inoperable defrosters or required trains to run at track speed in foggy conditions. *Id.* at 801.

[6] In making their relevance argument, Plaintiffs refer once to "findings" and twice to "violations" of CSA "duties." Opp. 57. The settlement agreements do not make findings and did not adjudicate violations.

Plaintiffs also argue that the settlements are admissible to prove "state of mind"—that "Defendants' conduct was intentional and persisted over a lengthy period of time." Opp. 55. But none of the settlements admits any *intentional* conduct and, as explained above, the small number of isolated agreements over a 20-year period hardly establishes a lengthy course of conduct. Plaintiffs' argument that the settlements are admissible to show Distributors' "state of mind"—*i.e.*, an alleged "pattern of conduct demonstrating knowledge by Defendants that their SOM systems were inadequate"—is similarly unavailing: the settlement do not contain admissions of any conduct relevant to Cuyahoga and Summit Counties and do not establish a pattern.

Finally, Plaintiffs argument that admission of the settlement agreements would not be unfairly prejudicial is flat-out wrong. Although inaccurate, it is plain that Plaintiffs intend to portray the settlement agreements as establishing that Distributors violated the CSA. While they blithely assert that "the jury is not likely to believe that an agreement with the government to settle what are in effect charges for CSA violations amount to an admission of liability to the alleged RICO [and] OCPA" claims, Plaintiffs have made clear that they intend to argue to the jury that supposed "CSA violations" *are* RICO/OCPA predicate acts.[7] It is difficult to imagine anything more prejudicial than the (false and misleading) suggestion to the jury that the federal government already has found Distributors liable for the very statutory violations that lie at the heart of Plaintiffs' claims (as they conceive them). *See, e.g.*, *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 800, 805 (6th Cir. 2007) (noting the "profound" impact "of evidence regarding a settlement agreement with regard to a determination of liability").

[7] Distributors do not agree that Plaintiffs have identified any provisions of the CSA whose violation would constitute a RICO predicate act.

2. [D-2] The Court Should Preclude Non-Party Corporate Representatives from Testifying to Matters Outside Their Personal Knowledge.

Distributors' motion seeks a ruling that non-party corporate representatives may not testify to matters outside their personal knowledge. Plaintiffs' opposition ignores the overwhelming weight of authority, as well as Rule 602, and instead relies on a single outlier district court decision. Plaintiffs then argue that the Court should reserve all decisions on this issue because, at trial, they *might* be able to offer a basis on which *some* of the challenged evidence is admissible—even though they are unable to identify even a single example of such evidence. This argument should be rejected.

As for *non-party* Rule 30(b)(6) testimony offered *at trial*—the type of testimony at issue in this motion—Plaintiffs point to one district court decision that is contrary to the weight of authority. *See* Opp. 60 (discussing *Sara Lee Corp. v. Kraft Foods*, 276 F.R.D. 500 (N.D. Ill. 2011)). The overwhelming majority of decisions on this issue—including from judges on this Court—hold that Rule 30(b)(6) testimony from a non-party is admissible at trial only if and to the extent it reflects the witness's personal knowledge. *See, e.g.*, *Cooley v. Lincoln Elec. Co.*, 693 F. Supp. 2d 767, 791 (N.D. Ohio 2010); *Stryker Corp. v. Ridgeway*, 2016 WL 6585007, at *2–3 (W.D. Mich. Feb. 1, 2016) (listing federal cases strictly applying Rule 602 to 30(b)(6) witnesses); *Universal Surveillance Corp. v. Checkpoint Sys., Inc.*, 2015 WL 6082122, at *27 (N.D. Ohio Sept. 30, 2015) (report by Special Master Cohen relying on *Cooley* to exclude testimony in which a witness failed to explain "how she obtained this new knowledge"). Unlike the *Sara Lee* decision on which Plaintiffs rely, these authorities align with Rule 602's personal knowledge requirement. *See Indus. Eng'g & Dev., Inc. v. Static Control Components, Inc.*, 2014 WL 4983912, at *4 (M.D. Fla. Oct. 6, 2014) ("Rule 30(b)(6) does not eliminate Rule 602's personal knowledge requirement.").

The other cases Plaintiffs cite are off-point. For example, they cite *Brazos River Authority v. GE Ionics, Inc.*, 469 F.3d 416, 435 (5th Cir. 2006), for the proposition that 30(b)(6) witnesses may testify broadly to corporate knowledge. *See* Opp. 59–60. But the Fifth Circuit has clarified that *Brazos* only applies to *deposition* testimony and the use of *that* deposition by "an *adverse* party ... during trial"; it does not apply to the testimony of a *third* party. *See Union Pump Co. v. Centrifugal Tech., Inc.*, 404 F. App'x 899, 907 (5th Cir. 2010) (emphasis in original). Plaintiffs' reliance on *PPM Finance, Inc. v. Norandal USA, Inc.*, 392 F.3d 889 (7th Cir. 2004), is ill-placed too, as that case involved a 30(b)(6) witness who actually *had* personal knowledge. *Id.* at 894 (witness "directly participated in calculating the financial statements" that were the basis of his testimony). Neither of these decisions help Plaintiffs because Distributors' motion does not seek to bar testimony for which the witness has personal knowledge. Instead, it seeks to bar testimony for which such foundation is absent.

The cases Plaintiffs cite involving summary judgment—and where the court determined that the matter presented through the witness's testimony was supported by documents relied upon by the witness that were themselves admissible—are similarly unhelpful to Plaintiffs. *See Lloyd v. Midland Funding, LLC*, 639 F. App'x 301, 305 (6th Cir. Jan. 22, 2016) (determining that documents relied upon were business records); *Univ. Healthsystem Consortium v. UnitedHealth Grp.*, 68 F. Supp. 3d 917, 922 (N.D. Ill. 2014) (determining admissibility of documents attached to affidavit and whether they were relied on for the testimony); *Pugh v. City of Attica, Ind.*, 259 F.3d 619, 627 n.7 (7th Cir. 2001) (holding document relied upon in interrogatory response was not inadmissible hearsay). In so holding, each court relied on the underlying documents themselves, not on a blanket acceptance of Rule 30(b)(6) testimony that itself lacked proper foundation.

Plaintiffs' effort to discount the examples from the Prevoznik deposition cited in Distributors' motion are no more successful. Prevoznik testified at deposition about a document that he had "never seen." Distrib. MIL at 7. Rather than offering any basis on which Prevoznik's testimony about this document could possibly be admissible, Plaintiffs respond by listing a number of potential bases on which the underlying document might itself be admissible. Opp. 61 n.56. But none of those bases, even if correct, would render admissible *Prevoznik's testimony* about the document, which he admitted he had never seen and about which he had no personal knowledge.

In the end, Plaintiffs' opposition does not identify even a single example of any non-party Rule 30(b)(6) testimony they seek to offer that is admissible in the absence of personal knowledge of the witness. Plaintiffs' speculation that such an example *might* be found to exist (Opp. 61) is insufficient to warrant denial of this motion.[8] Because such testimony is barred by Rule 602 and the overwhelming weight of authority, and because Plaintiffs' vague hypothesis about admissible exceptions is unsupported, Distributors' motion should be granted.

3. [D-3] The Court Should Exclude any Evidence of Criminal Indictments and Investigations without Corresponding Proof of a Final Judgment of Conviction.

Distributors' motion seeks exclusion of evidence of criminal indictments and investigation without proof of a conviction. It is beyond question—and the parties appear to be in full agreement—that the *fact* of an indictment, of grand jury proceedings, or of a criminal investigation is not admissible absent proof of a criminal *conviction*. *See* Distrib. MIL at 8; Opp. 63; *see also* Dkt. No. 2652 at 49–50; Dkt. No. 2725 at 53–54. Perhaps in recognition of this

[8] For this point, Plaintiffs cite a case in which no examples of testimony sought to be excluded were provided, which contrasts with the instant motion in which examples have been provided and discussed at length. *Compare Chimney Rock Pub. Power Dist. v. Tri-State Generation & Transmission Ass'n, Inc.*, 2014 WL 1583993, at *3 (D. Colo. Apr. 21, 2014) ("Defendant's Motion identifies no specific evidence it seeks to exclude . . . "), *with* Distrib. MIL at 7, *and* Dkt. No. 2756 at 1–4.

principle, Plaintiffs suggest that they "do not intend to introduce" indictments and related documents, "unless necessary for some other purpose, such as impeachment." Opp. 63. Contrary to the Plaintiffs' assertion, however, it is well-established that "[i]nquiry into the mere existence of an arrest or indictment is not admissible to impeach [a witness's] credibility." *United States v. Abadie*, 879 F.2d 1260, 1267 (5th Cir. 1989); *U.S. v. Maynard*, 476 F.2d 1170, 1174 (D.C. Cir. 1973) ("As a general rule, it is improper to impeach a witness by showing an outstanding indictment without a conviction").

Moreover, while there is no blanket rule precluding the admissibility of *facts* underlying a criminal indictment or investigation, such facts must be relevant to the issues in the case, and their probative value must outweigh the danger of unfair prejudice. *See* Fed. R. Evid. 402, 403. Plaintiffs reflexively suggest that whether Dave Gustin violated the CSA is "certainly relevant" to their claims. Opp. 63. Not so. Mr. Gustin's McKesson territory did *not* include Cuyahoga or Summit Counties.[9] Moreover, the allegation that Mr. Gustin violated the CSA is not an "underlying fact"—it is an unproven legal conclusion. Finally, Mr. Gustin's counsel has already informed the Court that, if called to testify, Mr. Gustin would invoke his Fifth Amendment right, *see* Dkt. No. 2795—which would have no probative value yet would be highly prejudicial to McKesson.[10]

[9] Mr. Gustin was not responsible for "compliance" (or anything else) at the New Castle Distribution Center, which accounted for more than 99 percent of McKesson's opioid shipments into Cuyahoga and Summit Counties, and which is part of McKesson' Northeast region. Mr. Gustin served as a director for a different region (North Central) that did not include Cuyahoga or Summit Counties.

[10] *See, e.g.*, *Akinyemi v. Napolitano*, 347 F. App'x 604, 607 (2d Cir. 2009) (upholding refusal to instruct jury on adverse inference against employer based on employee's invocation of Fifth Amendment); *Harrell v. DCS Equip. Leasing Corp.*, 951 F.2d 1453, 1465 (5th Cir. 1992) ("The potential prejudice in revealing the invocation of the Fifth Amendment is high, because the jury may attach undue weight to it, or may misunderstand [the witness's] decision to invoke his constitutional privilege."); *Coquina Investments v. Rothstein*, 2011 WL 13096509, at *1 (S.D. Fla. Oct. 19, 2011) (granting motion in limine excluding former employee's invocation of the Fifth Amendment; inference drawn from invocation of privilege "would not be trustworthy, and should be excluded under Rule 403 of the Federal Rules of Evidence").

4. [D-4] The Court Should Prohibit Plaintiffs from Stating Expressly or Suggesting that the Jury May Infer that an Older Document Never Existed Just Because It Cannot Be Found.

Distributors' motion seeks an order prohibiting Plaintiffs from stating expressly or suggesting that the jury may infer that an older document never existed just because it cannot be found. The opposition does not dispute that there is no requirement to retain suspicious order reports or due diligence records for any length of time, let alone *decades*, and acknowledges that Plaintiffs' DEA expert, James Rafalski, may not testify that such a requirement exists. Opp. 63–65; Dkt. No. 2494 at 8, 10. Plaintiffs should not be permitted to argue to the jury, directly or through their expert, that the absence of these decades-old records is evidence that the records never existed. That inference lacks any basis in law, is inconsistent with operative discovery rulings on which Distributors duly relied, and is unfairly prejudicial.

The opposition transparently reveals the "gotcha" game Plaintiffs are playing with due diligence documentation. Discovery Ruling No. 3 stated that "distributor defendants shall produce *transactional data* and *Suspicious Order Reports* with a cut-off date of January 1, 1996" and "shall produce *all other discovery* with a cut-off date of January 1, 2006." Dkt. No. 762 at 4. Notwithstanding the obligation to produce due-diligence documentation dating back only to 2006, Rafalski concluded, from the absence of documented due diligence before 2006 that Distributors did not do any:

> Q: On what basis are you saying that there was no due diligence done with regard to flagged orders? What is your basis for saying that?
>
> A: There were review of records submitted on discovery. … I don't want to say none whatsoever. I believe that probably there may have been some individual instances of due diligence, but in a general statement, at a systematic level, there was insufficient due diligence. Or none.
>
> Q: And what is your basis for saying that?

A: Reviewing records … [produced] by the drug companies under discovery.[11]

Plaintiffs' gambit is unfairly prejudicial. Plaintiffs' contention that 90 percent of all shipments to Cuyahoga and Summit County were suspicious depends on Rafalski's conclusion that Distributors did not perform due diligence. As Rafalski explained, "once the suspicious order is identified, the criteria I used is *if there was no due diligence to dispel the suspicious order … then every subsequent distribution would be a suspicious order*." Dkt. No. 1983-15, (Rafalski Tr.) 166:7–18. But given (i) Discovery Ruling No. 3, (ii) DEA's record-retention rules, and (iii) Distributors' own record-retention policies, absence of produced records pre-dating 2006 provides no basis on which to infer the absence of due diligence.

Plaintiffs' suggestion that the absence of records was not "the sole basis" for Rafalski's conclusion that Distributors did not conduct due diligence is baseless. In the deposition testimony cited above, Rafalski clearly stated that the basis for his conclusion that Distributors did not conduct due diligence was his review of documents produced in discovery. And the same is true for his expert report: Rafalski's conclusions about Distributors' lack of due diligence are based on the absence of documentation before 2006—documents that Distributors had no obligation to retain or produce. Dkt. No. 1899-19 (Rafalski Rpt.) 51 (stating that "Cardinal's due diligence prior to 2006 is very limited, and it is difficult to discern exactly what due diligence was conducted by Cardinal prior to 2006.").

Finally, the opposition does not even address Distributors' arguments with respect to suspicious order reports—the only records other than transactional data that Distributors were obligated to produce back to 1996. The obligation to produce reports plainly applied only to the extent such reports still exist. But Distributors' record-retention requirements (imposed both by

[11] Dkt. No. 1983-15 (Rafalski Tr.) 168:19-169:7.

DEA and their own internal corporate policies) did not require that they retain these decades-old reports. And as DOJ Inspector General's recent report revealed, not even the *DEA* retains suspicious order reports.[12] DEA field division staff "were unaware of the requirement to maintain the [suspicious order] reports and could not locate them." *Id.*

For these reasons, the Court should prohibit Plaintiffs from stating or suggesting that the jury may infer that an older document never existed just because it was not produced in discovery.

5. [D-5] The Court Should Prohibit Plaintiffs from Presenting Evidence or Making Arguments Suggesting Distributors Committed a "Fraud On the DEA."

Distributors' motion seeks to prohibit Plaintiffs from presenting evidence or making arguments suggesting that Distributors committed a "fraud on the DEA." Plaintiffs have disclaimed pursuing claims based on "fraud on the DEA," and this Court has held that Plaintiffs' claims do not concern "fraud on the DEA," Dkt. No. 2565 at 9, 22. Plaintiffs cannot pursue claims based on "fraud on the DEA" because such claims would be preempted under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001). Distributors' motion seeks to ensure that Plaintiffs will not make "fraud on the DEA" arguments at trial disguised as different legal claims or theories, thus improperly conducting an end-around *Buckman*.

Plaintiffs argue that *Buckman* "does not render evidence regarding [Distributors'] interactions with the DEA irrelevant or inadmissible." Opp. 65. But Distributors did not say that it was. Distributors do not seek a broad ruling that any and all evidence regarding their interactions with the DEA is inadmissible. Instead, Distributors reasonably seek a very specific ruling that Plaintiffs may not offer any testimony, evidence, or argument that Distributors have

[12] Ex. A (Office of the Inspector General, United States DOJ, *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids*, 19-05, September 2019).

committed fraud on the DEA or misled the DEA by failing to report suspicious orders or otherwise failing to submit required information. This is a non-controversial proposition—indeed, Plaintiffs say that they are not pursuing claims based on fraud on the DEA, and this Court has held that Plaintiffs' claims do not concern fraud on the DEA. Any testimony, evidence, or argument that Distributors have committed fraud on the DEA or misled the DEA by failing to report suspicious orders or otherwise failing to submit required information would be irrelevant, prejudicial, and would risk confusing the jury.

6. [D-6] The Court Should Prohibit Counsel and Witnesses from Making References Broadly and Generally to "Defendants" When the Statement, Argument, or Testimony Relates Only to Certain Specific Defendants or Groups of Defendants.

Distributors' motion seeks to prohibit counsel and witnesses from making broad references to "Defendants" when the statement, argument, examination question, or testimony relates only to a specific defendant or group of defendants. Imprecise and overly-broad references by experts in this case already have led to confusion. *See* Distrib. MIL at 16. Such careless lumping of "Defendants" violates Rule 403 because it threatens to unfairly prejudice Distributors, confuse the issues, mislead the jury, cause undue delay, waste time, and result in the needless presentation of cumulative evidence.

Plaintiffs contend that they should be permitted to make statements lumping Defendants together. Plaintiffs argue that a prohibition on such references would require counsel to approach the bench before using the word "defendants" and would impede the flow of trial. Opp. 67–68. Not so. There is no reason why counsel would ever need to approach the bench over this issue, let alone each time counsel wanted to refer to a defendant. For the sake of fairness and clarity, Plaintiffs simply need to be precise when they are speaking about a specific defendant or a specific subset of defendants. Furthermore, prohibiting counsel and witnesses

from making broad references to "Defendants" when the statement relates only to specific defendants can only save time and judicial resources. If Plaintiffs are permitted to lump Defendants together with their statements at trial, it would force individual defendants to use valuable court time to cross-examine witnesses to clarify how they are using "defendants" and object often to counsel's use of the generic term "defendants." Plaintiffs acknowledge as much, stating that individual defendants should try to reduce prejudice and confusion "through cross-examination" and by "individual objections at trial." Opp. 68.[13]

Plaintiffs' opposition fails to address the primary reasons why a prohibition on making broad references to "Defendants" when the statement relates only to specific defendants is necessary here:

Unfair Prejudice – Attributing bad facts (such as those pertaining to "misrepresentation" and "misleading messaging") to parties that took no part in such action risks unfairly prejudicing the jury against those parties.

Confusing the Issues and Misleading the Jury – Lumping prevents a jury from properly allocating liability to individual defendants when they are entirely distinct entities.

Undue Delay and Wasting Time – If each individual defendant is forced repeatedly to stave off misunderstandings, such efforts inevitably will waste time at trial that already is in short supply.

[13] Plaintiffs quote an Oregon district court case to support their argument, but Plaintiffs misleadingly use an ellipsis to make the case seem on-point when it is not. *See Flir Sys., Inc. v. Fluke Corp.*, 2012 WL 13054267, at *5 (D. Or. Nov. 29, 2012) ("It would be highly impractical to enforce this motion at trial. Absent a legitimate basis to preclude the use of a particular term *to describe the video*, it is for counsel to choose the words they prefer to describe it.") (emphasized words omitted with an ellipsis from Plaintiffs' opposition).

7. [D-7] The Court Should Preclude Plaintiffs from Offering Evidence of, and Arguments about, RICO Predicates that Plaintiffs Did Not Identify in Their Discovery Responses.

Distributors' motion seeks to exclude any argument or testimony regarding "RICO predicates that Plaintiffs did not identify in their discovery responses." Plaintiffs' principal response to this motion is a non-sequitur.

Plaintiffs argue that they adequately disclosed, in their complaints and interrogatory responses, several categories of RICO predicate acts—but that is not in dispute. Distributors agree that Plaintiffs disclosed their reliance on the mail and wire fraud statutes, and do not seek to exclude evidence or argument relating to mail or wire fraud through this motion. Distributors likewise agree that Plaintiffs identified violations of 21 U.S.C. § 843(a)(4)—which prohibits "furnishing false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under" the CSA—as constituting "the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance" in their complaints and interrogatory responses. While Distributors disagree with the Court's ruling that violations of Section 843 may constitute predicate acts, this motion does not seek to preclude Plaintiffs from offering evidence or argument relating to purported violations of 21 U.S.C. § 843(a)(4) as undisclosed.[14]

In Plaintiffs' proposed jury instructions, however, they also seek an instruction that violations of 21 U.S.C. § 823 and 21 U.S.C. § 841, among other provisions, constitute predicate acts.[15] *Those* predicate acts were not disclosed by Plaintiffs, either in their complaints or in their

[14] As explained in Defendants' MIL No. 7, Plaintiffs' evidence regarding alleged failures to notify DEA of suspicious orders is not relevant to their claim involving 21 U.S.C. § 843(a)(4) because that provision concerns only failures to make reports required under subchapter I or II of the CSA, and those subchapters did not require the reporting of suspicious orders. *See* Dkt. No. 2661 at 18–19.

[15] The OCPA incorporates RICO's predicate act provisions in relevant part. Accordingly, a ruling that violations of 21 U.S.C. § 823 and 21 U.S.C. § 841 do not constitute RICO predicate acts would necessarily apply to any OCPA claim premised upon violations of those federal statutes.

interrogatory responses. And Plaintiffs' opposition tellingly fails to offer any argument that Plaintiffs should be permitted to introduce evidence or arguments regarding *those* categories of predicate acts. Fundamental fairness requires that they should not.[16]

Finally, Plaintiffs are wrong that Distributors' motion "rests on a misapplication of the law." The cases cited in Distributors' motion hold that plaintiffs may not rely on undisclosed RICO predicate acts in order to defeat summary judgment. The principle underlying those decisions apply with even greater force here, where Plaintiffs seek to rely on undisclosed predicate acts at trial. *See State Farm Mut. Auto. Ins. Co. v. Physiomatrix, Inc.*, 2014 WL 10294813, at *5 n.7 (E.D. Mich. Apr. 24, 2014) (denying plaintiff's motion to add to "the alleged predicate acts" because the request constituted an attempt "to materially change the complexion of the case"); *Feminist Women's Health Ctr. v. Roberts*, 1988 WL 156656, at *11 (W.D. Wash. Mar. 11, 1988) (granting defendants' motion for summary judgment for RICO claims based on plaintiffs' failure to "cite the specific statutes on which they base their assertions of predicate acts"); Fed. R. Civ. P. 37(c)(1) ("If a party fails to provide information …, the party is not allowed to use that information … to supply evidence… at a trial, unless the failure was substantially justified or is harmless.").

8. [D-8] The Court Should Issue an Order Excluding any Evidence of, or Reference to, Distributor-Run Programs that Allowed Manufacturers To Communicate Product Information to Pharmacies or Other Parties.

Distributors' motion seeks an order excluding evidence of Distributor-run programs that allow manufacturers to communicate product information. Plaintiffs' opposition fails to argue, and therefore concedes, the primary point of Distributors' motion: evidence and argument

[16] Plaintiffs' assertion that Distributors "made this same argument in the motion to dismiss phase of the case and the Court rejected it" is pure make-believe. The *only* predicate acts discussed in Distributors' motion to dismiss were (1) mail fraud, (2) wire fraud, and (3) violations of Section 843(a)(4)—because those were the only predicate acts pled in Summit County's complaint.

related to certain programs offered by Distributors to provide product information to pharmacies is both (1) irrelevant to Plaintiffs' claims against Distributors and (2) would prejudice Distributors and confuse the jury. *See* Fed. R. Evid. 403. In light of these concessions, exclusion of this evidence is entirely appropriate.

Plaintiffs claim that these materials are relevant to their claims against *Manufacturers*. But Plaintiffs' marketing claims against Manufacturers relate to alleged misleading marketing to doctors and patients and attempts to change the standard of care for prescribers. Dkt. No. 2182 at 1 (claims against Manufacturers based on their "fraudulent marketing campaign … for the purpose of expanding the opioid market"). Distributors had no role in these activities. To the contrary, Distributors' programs were limited to providing certain product information to pharmacies, not prescribers; programs that, as Plaintiffs' experts admit, were not intended to "generate patient level demand." Perri Tr. (Dkt. No. 1983-4) at 217:21–218:3, 224:19–20.[17] By conflating Distributors' programs with the very different types of marketing by Manufacturers, Plaintiffs have proven Distributors' point. The possibility for jury confusion is paramount, and Plaintiffs' opposition makes clear that they will foster that confusion by trying to conflate these very different "marketing" activities. *See Deskovic v. City of Peekskill*, 673 F. Supp. 2d 154, 171 (S.D.N.Y. 2009) (warning against "spill-over" prejudice).

Plaintiffs' opposition further illustrates the overwhelming risk of juror confusion by arguing that Distributors and Manufacturers "have different roles in the conspiracy." Opp. 71. This statement ignores that Plaintiffs *separately* allege the existence of (1) a "Marketing Enterprise," in which Distributors were not involved, and (2) a distinct "Supply Chain

[17] Plaintiffs attack Distributors' account of Dr. Perri's testimony as "inaccurate" yet fail to identify any inaccuracies. Opp. 71 & n.65. Indeed, it is Plaintiffs that misrepresent Dr. Perri's testimony. For example, Plaintiffs represent Dr. Perri testified "that 'the marketing of opioids was inappropriate' with the distributors being 'part of that process,'" *id.*, but omit his explanation that "*from a macro perspective,* the wholesalers were implicated in that marketing *because of their role—their integral role in the supply chain*." Perri Tr. (Dkt. No. 1983-4) at 222:7–10.

Enterprise," which was not allegedly involved in the purportedly fraudulent marketing campaign. Such blurring of the distinction between the alleged "Marketing Enterprise" and "Supply Chain Enterprise" is exactly the sort of prejudice Rule 403 protects against.[18] *See Sidari v. Orleans Cnty.*, 174 F.R.D. 275, 282 (W.D.N.Y. 1996) ("A lumping together of such claims, which amounts to guilt by association, would unfairly prejudice the defendants.").

Tellingly, Plaintiffs do not dispute that this evidence will prejudice Distributors by confusing the jury and causing them to assign blame for the alleged "Marketing Enterprise" to Distributors. Instead, Plaintiffs argue a jury instruction can mitigate the prejudice. But a jury instruction is insufficient to cure such significant prejudice, especially because Plaintiffs exacerbate that prejudice by implying Distributors were involved in Manufacturers' allegedly fraudulent marketing. *See United States v. Solivan*, 937 F.2d 1146, 1156 (9th Cir. 1991) ("isolated remarks … may be so prejudicial that no cautionary instruction, however swiftly and forcibly given, can safely eradicate [their] effect"). Accordingly, the Court should exclude trial exhibits and testimony relating to Distributor-run programs that allowed manufacturers to communicate their product information to pharmacies and other parties.

At an absolute minimum, the Court should exclude evidence relating to marketing programs involving severed and settled Defendants. Even accepting as true Plaintiffs' assertion that these materials are "directly relevant to Plaintiffs' claims against the Manufacturers who created the advertisements," that provides no basis for the admission of—for example—pharmacy advertisements relating to Endo or Mallinckrodt products. Such materials plainly are

[18] While conceding that their case against Distributors has no relation to any alleged marketing, Plaintiffs also claim, inexplicably, that they seek to use the evidence "to demonstrate [Distributors'] overall motive and knowledge." Opp. 70. This is a non sequitur. Plaintiffs have offered absolutely no explanation as to how certain programs providing product information to pharmacists are relevant to the "Supply Chain" Enterprise's alleged "motive" to ship opioid orders while avoiding regulatory oversight by the DEA. Nor can Plaintiffs point to any shred of evidence in the record that Distributors had "knowledge" that the content of many of the manufacturer marketing materials were misleading.

not relevant, would foster jury confusion, and would force Distributors to use a portion of the precious little time they have been allotted for their defense to address claims of fraudulent marketing asserted against absent parties.

III. CONCLUSION

For the reasons stated above, Distributors request that the Court grant Distributors' Omnibus Motions in Limine.

Dated: October 14, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Robert A. Nicholas, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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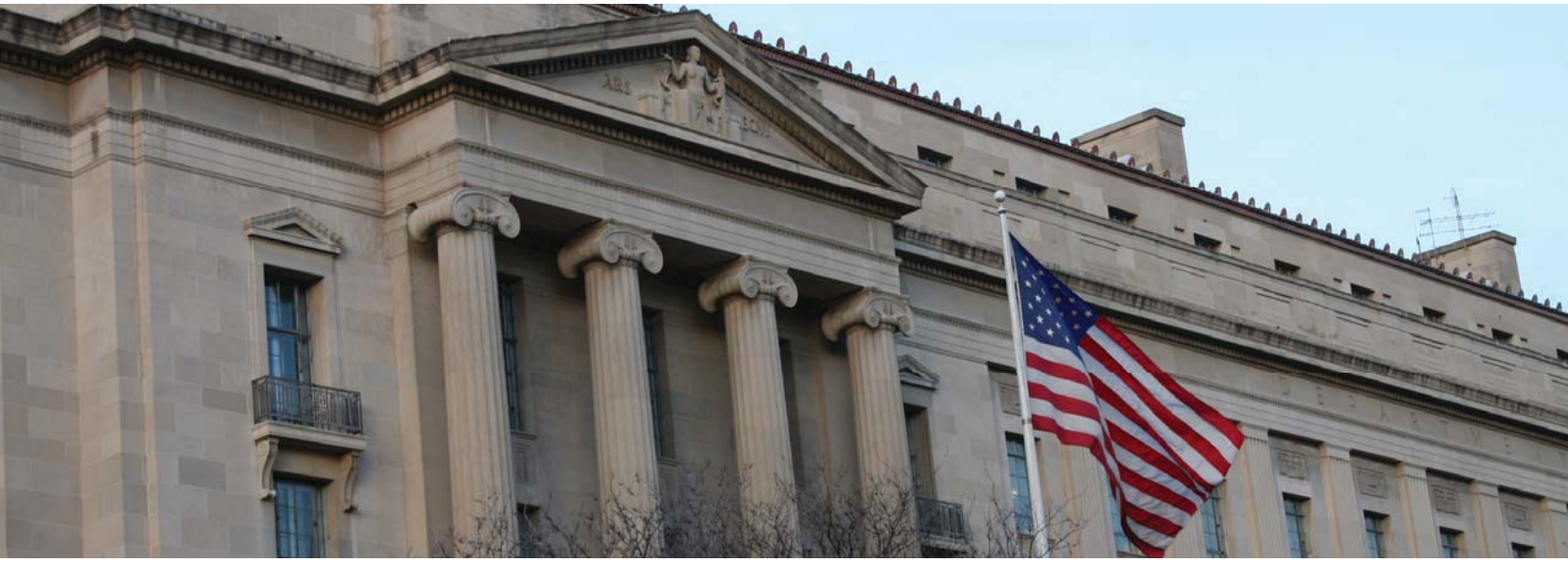
EXHIBIT A

Office of the Inspector General
U.S. Department of Justice

OVERSIGHT ★ INTEGRITY ★ GUIDANCE



Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids

Evaluation and Inspections Division 19-05 September 2019

Executive Summary

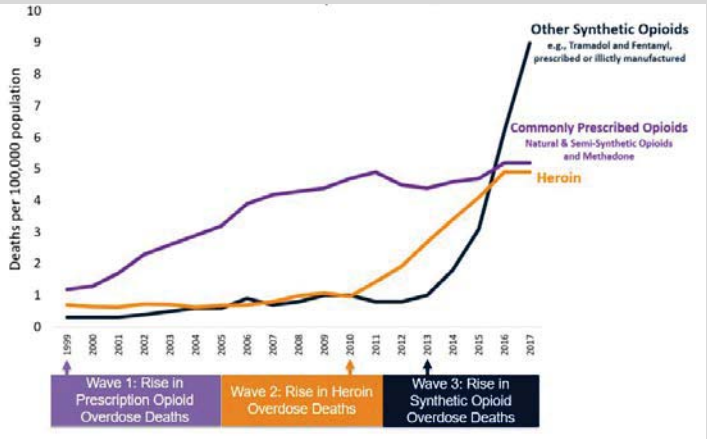
Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids

Introduction

In this review, the Office of the Inspector General (OIG) examined the regulatory activities and enforcement efforts of the Drug Enforcement Administration (DEA) from fiscal year (FY) 2010 through FY 2017 to combat the diversion of opioids to unauthorized users. According to the Centers for Disease Control and Prevention (CDC), as of 2017 in the United States more than 130 people die every day from opioid overdose. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose. The misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl, has led to a national crisis that affects not only public health, but also the social and economic welfare of the country. As a result, in October 2017 the White House declared the opioid epidemic a public health emergency.

Figure 1

The Three Waves in the Rise of Opioid Overdose Deaths



Source: CDC National Vital Statistics System Mortality File

DEA enforces Titles II and III of the Controlled Substances Act of 1970 (CSA), which require importers, exporters, manufacturers, distributors, dispensers, and healthcare practitioners that handle controlled substances, collectively known as registrants, to register with DEA. DEA's Office of Diversion Control is responsible for ensuring that all controlled substance transactions take place within the closed system of distribution established by Congress. When controlled substance transactions fall outside the closed system of distribution, the activity constitutes diversion. Registrants that violate the CSA or its implementing regulations may be subject to DEA administrative enforcement actions or may face civil penalties or criminal prosecution by the U.S. Department of Justice (Department).

Results in Brief

We found that DEA was slow to respond to the significant increase in the use and diversion of opioids since 2000. We also found that DEA did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively. Further, we found that DEA policies and regulations did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids. Lastly, we found that while the Department and DEA have recently taken steps to address the crisis, more work is needed.

DEA Was Slow to Respond to the Dramatic Increase in Opioid Abuse and Needs to More Fully Utilize Its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances

We found that the rate of opioid overdose deaths in the United States grew, on average, by 8 percent per year from 1999 through 2013 and by 71 percent per year from 2013 through 2017. Yet, from 2003 through 2013 DEA was authorizing manufacturers to produce substantially larger amounts of opioids. For example, the Aggregate Production Quota (APQ) of oxycodone in the United States, which DEA establishes annually, increased over 400 percent between 2002 and 2013. It was not until 2017 that DEA significantly reduced the APQ for oxycodone, by 25 percent. In 2018, DEA further reduced the APQ for oxycodone by 6 percent.

We identified other areas in which DEA's regulatory and enforcement efforts could have been more effective in combating opioid diversion. First, DEA's preregistration process did not adequately vet all new applicants before DEA registration was granted. Second, we found that DEA has regulations that fail to assess the suitability of potential new registrants, which may prevent DEA from identifying registrants whose applications merit heightened scrutiny. Third, while electronic prescriptions can prevent prescription fraud in many instances, DEA has not taken steps to revise its regulations and require all prescribers to submit prescriptions electronically. Fourth, stringent DEA headquarters requirements for field divisions to complete their headquarters-assigned Diversion Control work plans left little room for targeting registrants suspected of diversion. Finally, beginning in 2013, DEA rarely used its strongest enforcement tool, the Immediate Suspension Order, to stop registrants from diverting prescription drugs and DEA continues to experience challenges in rendering timely final decisions in administrative actions against registrants for diversion and other alleged violations.

Executive Summary

Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids

Improved Data Systems Would Facilitate Better Detection of the Diversion of Pharmaceutical Opioids and New Opioid Analogues

We found that DEA does not capture sufficient data to detect the diversion of opioids or emerging drug trends in a timely manner. DEA investigators rely on a number of databases, including the Automated Reports and Consolidated Orders System (ARCOS) and the Suspicious Order Reporting System (SORS), to identify emerging trends in diversion and drug abuse.

We found multiple deficiencies in ARCOS data. Specifically, because some registrants report ordering information to ARCOS on a monthly or quarterly basis, DEA often must wait a full year before ARCOS contains all of the ordering information DEA needs to fully analyze the data and develop leads and trends. In addition, ARCOS does not track the diversion of all pharmaceuticals, including some Schedule III and all Schedule IV and V opioids and other controlled substances. As a result, DEA cannot create ARCOS targeting packages for those drugs and is not tracking drugs, such as benzodiazepines, which are Schedule IV controlled substances often used in conjunction with opioids. Due to these deficiencies, we believe that DEA is ill-equipped to effectively monitor ordering patterns for all pharmaceutical opioids, which could enable the diversion of these prescription drugs and compromise public safety.

We also found that the SORS database, developed in 2008 to house suspicious order reports that federal regulations require manufacturers and distributors of controlled substances to send to DEA, is incomplete and therefore cannot be used effectively to detect diversion. We determined that this was due to the fact that most suspicious order reports are sent to DEA field divisions and that those reports are never uploaded into the SORS database. As a result, of the approximately 1,400 manufacturers and distributors required to report suspicious orders to DEA, the SORS database included reports from only the 8 manufacturers and distributors that had agreements with DEA to send such reports to DEA headquarters. When we asked DEA for records of suspicious orders reports sent to field divisions rather than headquarters, DEA was unable to locate them.

We did, however, find that DEA is currently working more closely with its federal partners, including the U.S. Department of Health and Human Services (HHS) and the HHS Office of Inspector General, to obtain the data it needs to identify diversion through Medicare billing records. Collaboration with federal partners also enhances DEA's data sharing capabilities, which facilitates data-driven oversight and improves regulatory oversight. However, we also learned that DEA faces challenges accessing states' Prescription Drug Monitoring Programs (PDMP), which contain physician and patient prescription histories. The level of DEA access to PDMP data varies across states; however, if DEA had greater access to this information, while also ensuring protection of sensitive patient medical data, DEA could improve its ability to investigate registrants that may be diverting pharmaceutical opioids. Further, we found that DEA must continue to improve its information sharing with state and local medical and pharmacy boards to ensure that all parties are aware of enforcement actions against registrants that may have violated conditions of their state licenses or registrations.

The Department and DEA Have Taken Steps to Address the Opioid Epidemic as a National Crisis

We found that the Department and DEA have recently taken steps to address the opioid epidemic, but more work remains. For example, in November 2015 DEA implemented its 360 Strategy, which focuses on law enforcement coordination, diversion control and regulatory enforcement efforts, and community outreach. However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine whether the program's diversion-related activities have improved its field offices' diversion control enforcement capabilities.

We also found that DEA has taken steps to increase enforcement staffing and enforcement actions. In response to a national decline in enforcement staffing, DEA is making an effort to increase both Diversion Investigator and Special Agent staffing levels in the field divisions hardest hit by the opioid epidemic. DEA also conducted a 45-day enforcement surge that resulted in 273 enforcement actions, although we found that some of these actions were scheduled investigations that were routinely conducted as part of DEA's annual Diversion Control work plan. Additionally, the Department's Opioid Fraud and Abuse Detection Unit started providing targeting packages to 12 U.S. Attorney's Offices (USAO). As a result, we were told that USAOs have been able to generate leads and supplement ongoing DEA investigations.

Recommendations

In this report, we make 9 recommendations to improve the Department's and DEA's ability to combat the diversion of pharmaceutical opioids and effectively target and regulate registrants that engage in diversion.

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INTRODUCTION

The Office of the Inspector General (OIG) undertook this review to assess the Drug Enforcement Administration's (DEA) regulatory activities and enforcement efforts involving opioid manufacturers, distributors, doctors, and pharmacies. We examined whether DEA's efforts effectively prevented registrants from diverting controlled substances, particularly opioids, from fiscal year (FY) 2010 through FY 2017.[1]

Background

DEA's Diversion Control Program seeks to prevent, detect, and investigate the redirection of controlled pharmaceuticals and listed chemicals from illegitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

According to DEA, controlled pharmaceuticals can be diverted from legitimate channels through theft or fraud during the manufacturing and distribution process by anyone involved in the process, including medical and pharmacy staff and individuals involved in selling or using pharmaceuticals.[2] Registrants that violate the CSA or its implementing regulations may be subject to DEA administrative enforcement actions or, depending on the seriousness of the violations, face civil penalties or criminal prosecution by the U.S. Department of Justice (Department, DOJ).[3]

In recent years, the United States has confronted one of the worst drug epidemics in its history. According to the Centers for Disease Control and Prevention (CDC), in 2017 the United States experienced more than 70,237 overdose deaths, of which 47,600 (67.8 percent) involved an opioid, averaging 130 opioid overdose deaths each day.[4] National Institute on Drug Abuse data also shows that nearly 80 percent of people who began abusing illicit opioids

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[1] While OIG did assess DEA's enforcement efforts with respect to pharmaceutical opioids, we did not assess these efforts with regard to illicit opioids such as heroin nor did we examine DEA's transnational trafficking and money laundering operations involving synthetic opioids such as fentanyl and fentanyl analogues. For more information about these topics, see U.S. Government Accountability Office (GAO), *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts,* GAO-18-205 (March 2018), www.gao.gov/assets/700/690972.pdf (accessed September 25, 2019).

[2] DEA defines "diversion" as any activity whereby legitimately made controlled substances that are intended to be used for lawful purposes are sold or exchanged in the illegitimate drug market as illicit substances. Controlled substances are contained in Drug Schedules I–V and are regulated by DEA.

[3] 21 U.S.C. § 801 et seq. and 21 C.F.R. § 1300 et seq.

[4] CDC, "Drug Overdose Deaths in the United States, 1999–2017," www.cdc.gov/nchs/products/databriefs/db329.htm, and "Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017," www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w (both accessed September 25, 2019).

during the 2000s started by abusing a prescription opioid.[5] Further, misuse of and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids such as fentanyl, has led to a serious national crisis that affects not only public health but also the social and economic welfare of the country. For example, according to the National Institute on Drug Abuse, the economic burden of the opioid epidemic is an estimated $78.5 billion every year, with state and local governments funding 25 percent of that burden.[6] In addition, increased healthcare and substance abuse treatment costs contributed $28.9 billion to this economic burden, with over 14 percent of the aggregate costs of the opioid epidemic being funded by public health insurance programs such as Medicare, Medicaid, and Veterans Administration benefits.[7]

Below, we provide a historical perspective on the opioid epidemic. We also describe DEA's management of its Diversion Control Program through a closed system of distribution within the regulatory population, its reporting databases, registrant enforcement actions, and overall efforts to combat the opioid epidemic.

Historical Perspective on the Opioid Epidemic

In October 2017, with pharmaceutical prescription drugs and illicit opioids such as heroin contributing to more than 300,000 overdose deaths in the United States since 2000, the White House declared the opioid epidemic a public health emergency.[8] CDC has reported that from 2000 through 2014 drug overdose deaths increased by 137 percent, including a 200 percent rise in overdose deaths involving opioids due to the abuse of pain relieving prescription drugs and heroin.[9] In fact, the rate of drug overdose deaths involving prescription opioids other than methadone increased by 45 percent from 2016 through 2017.[10]

Origin of the Opioid Epidemic: The OxyContin® Crisis of the Late 1990s and Early 2000s

During the late 1990s and early 2000s, the abuse of prescription drugs was a growing problem. In 1998, 2.5 million Americans admitted to abusing prescription

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[5] National Institutes of Health (NIH) National Institute on Drug Abuse, "Prescription Opioids and Heroin," www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (accessed September 25, 2019).

[6] NIH National Institute on Drug Abuse, "Opioid Overdose Crisis," www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (accessed September 25, 2019).

[7] NIH National Institute on Drug Abuse, "Opioid Overdose Crisis."

[8] White House, "Ending America's Opioid Crisis," www.whitehouse.gov/opioids (accessed September 25, 2019).

[9] CDC, "Increase in Drug and Opioid Overdose Deaths—United States, 2000–2014," www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (accessed September 10, 2019).

[10] CDC, "Drug Overdose Deaths in the United States, 1999–2017."

drugs, and by 2001 that number had nearly doubled to 4.8 million.[11] DEA estimated that by 2003 the number of people who were abusing prescription drugs roughly equaled the number who abused cocaine, which was about 2–4 percent of the U.S. population.[12]

For example, according to DEA, OxyContin was one of the most abused prescription drugs of the late 1990s and early 2000s. In 1996, pharmaceutical manufacturer Purdue Pharma introduced OxyContin as a time-released form of oxycodone to treat people with chronic pain. DEA told us that OxyContin was being diverted through fraudulent prescriptions; over-prescribing; theft and illegal sales; and "doctor shopping," the practice of going to different doctors until one prescribes the narcotic the patient seeks. According to DEA, OxyContin became a target for diverters and abusers due to its large amount of oxycodone and the ability of abusers to easily compromise its controlled release mechanism.[13] Simply crushing a tablet negates the timed effect of the drug, enabling abusers to swallow, inhale, or inject the drug for a powerful, morphine-like high. In 2009, the U.S. Department of Health and Human Services' (HHS) Drug Abuse Warning Network Live (DAWN Live) reported that emergency room visits for oxycodone overdoses were more than 100 percent higher in 2000 than in 1998.[14]

The President's Commission on Combating Drug Addiction and the Opioid Crisis noted in its June 2018 report to the President that the large-scale manufacture and distribution of opioids during the 1990s was one factor that led to overprescription of painkillers.[15] Further contributing to the opioid epidemic at that time were "black tar" heroin networks and the proliferation of pill mill medical

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[11] DEA, "History, 1999–2003," 91, www.dea.gov/sites/default/files/2018-07/1999-2003%20p%2091-118.pdf (accessed September 25, 2019).

[12] DEA, "History, 1999–2003," 113.

[13] A controlled release mechanism (in contrast to immediate-release dosage) delivers a drug delayed, over a prolonged period of time or to a specific part of the body (targeted-release dosage). Controlled release was put in place for OxyContin to prevent the user from achieving a "high," or feeling of euphoria, upon its immediate release into the bloodstream.

[14] DAWN gathered information from hospitals, emergency rooms, and medical examiners to monitor trends in the types of drugs being abused and patterns of abuse in certain areas. HHS discontinued DAWN in 2011.

[15] White House, *The President's Commission on Combating Drug Addiction and the Opioid Crisis* (November 2017), 20, www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf (accessed September 25, 2019). According to this report:

> Aggressive promotion of an oxycodone brand from 1997–2002 led to a 10-fold rise in prescriptions to treat moderate to severe noncancer pain, and increases in prescribing of other opioids. Subsequently, the highest strengths permissible was increased for opioid-tolerant patients, likely contributing to its misuse.... It has been hypothesized that the marked rise in heroin and other illicit synthetic opioids is, in part, associated with unintended consequences of reformulation of OxyContin, and a reduced supply and greater expense of prescription opioids.

clinics (sometimes called pain management clinics).[16] (See the text box for a timeline of the opioid epidemic).

Timeline of the Opioid Epidemic

1984: Purdue Pharma releases MS Contin, a time-released morphine painkiller marketed to cancer patients.

1995: The U.S. Food and Drug Administration (FDA) approves OxyContin for use in the United States.

1996: Purdue Pharma releases OxyContin, time-released oxycodone, which is marketed largely for chronic pain.

1998: FDA approves Actiq (fentanyl), the first pain medicine approved to treat cancer breakthrough pain.

1997–2002: OxyContin prescriptions for non-cancer related pain increase from about 670,000 in 1997 to about 6.2 million in 2002.

2000: Xalisco black tar heroin networks emerge; during the scope of our review, they still existed in at least 17 states.

Mid-2000s: Operation Tar Pit, the largest joint DEA/Federal Bureau of Investigation operation and first drug conspiracy case to stretch from coast to coast, targets Xalisco heroin networks.

2006: DEA launches Operation Black Gold Rush, a second operation targeting Xalisco heroin networks across the country.

2007: Purdue Pharma and three of its executives plead guilty to misdemeanor charges of false branding of OxyContin and are fined $634 million.

2008: Drug overdoses, mostly from opiates, surpass auto fatalities as a leading cause of accidental death in the United States.

2014: FDA approves Zohydro, a time-released hydrocodone painkiller with no abuse deterrent. It also approves Purdue Pharma's Targiniq ER, the opiate abuse antidote that combines time-released oxycodone with naloxone.

Sources: Quinones, *Dreamland,* and FDA

DEA's Response to the OxyContin Crisis

To combat the growing OxyContin crisis, in the spring of 2001 DEA initiated an OxyContin National Action Plan.[17] According to DEA, this was the first time in DEA's history that it developed a plan to target a brand-specific controlled substance with a focus on enforcement and regulatory investigations that targeted key points of diversion. The plan directed DEA field divisions and DEA's Office of Diversion Control (OD) to conduct in-depth investigations of OxyContin's manufacturer and distributors to determine their compliance with regulatory requirements designed to prevent diversion.[18] The plan also sought to coordinate enforcement and intelligence sharing with federal, state, and local agencies; take regulatory and administrative action to limit abusers' access to OxyContin; and

[16] "Black tar" heroin is a generally less expensive form of heroin that is dark in color and sticky like tar. Pill mills are clinics that distribute—without a legitimate medical purpose—large amounts of controlled substances such as painkillers or antianxiety medications. Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* (New York: Bloomsbury Press, 2015).

[17] DEA Office of Diversion Control (OD), "OxyContin®: Diversion and Abuse," October 2003, www.media.washingtonpost.com/wp-srv/politics/documents/giuliani_dea_action_plan_oct2003.pdf (accessed September 25, 2019).

[18] In September 2016, the OD was restructured and became known as the Diversion Control Division. For purposes of consistency in this report, we refer to this division as OD because that was the name of the division during the majority of our review period.

conduct outreach, awareness, and education initiatives to educate the public on the dangers of abusing OxyContin.

According to a 2003 U.S. Government Accountability (GAO) report, part of DEA's National Action Plan set the Procurement Quota for oxycodone at levels lower than requested by Purdue Pharma, OxyContin's manufacturer.[19] Specifically, when OxyContin was first introduced to the market in 1996, DEA granted Purdue Pharma's initial Procurement Quota request but began to notice dramatic increases in sales. As a result, DEA required Purdue Pharma to provide additional information to support its requests to increase the quota and DEA set the Procurement and Aggregate Production Quotas for oxycodone at lower levels in 2002. However, in the years following the OxyContin crisis, DEA increased the Aggregate Production Quota (APQ) for oxycodone, which we discuss later in this report. DEA told GAO about the difficulty it had faced in determining an appropriate Production Quota level that ensured that adequate quantities were available for legitimate medical use while also seeking to limit abuse and diversion.[20]

GAO reported that other federal agencies, including the U.S. Food and Drug Administration (FDA), also took action in response to the OxyContin crisis. In April 2001, FDA and Purdue Pharma developed a risk management plan to help detect and prevent the abuse and diversion of OxyContin.[21] The plan ultimately strengthened the safety, or "black box," warnings on OxyContin's label for professionals and patients; required training for Purdue's sales force on the revised label; directed that Purdue conduct comprehensive education programs for healthcare professionals; and directed Purdue to develop a database for identifying and monitoring abuse and diversion of OxyContin. Purdue also reiterated to its sales representatives that failure to promote products according to the approved label, promotional materials, and applicable FDA standards would result in disciplinary action by the company.[22]

Despite these responses by DEA and other federal agencies to the OxyContin crisis, since the early 2000s there has been a steady increase in the rate of opioid overdose deaths caused by natural and semisynthetic opioids, such as oxycodone and hydrocodone, which coincided with an increase in the production quotas for these controlled substances. We specifically discuss the increase in the APQ for oxycodone later in this report. Since approximately 2010, the rate of overdose

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[19] The Procurement Quota is issued to registered manufacturers that desire to obtain any Schedule I and/or II basic class of controlled substances in order to further manufacture that substance by packaging, repackaging, labeling, relabeling, or using it to produce dosage forms or other substances. See 21 C.F.R. § 1303.13.

[20] GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem,* GAO-04-110 (December 2003), www.govinfo.gov/app/details/GAOREPORTS-GAO-04-110 (accessed September 25, 2019).

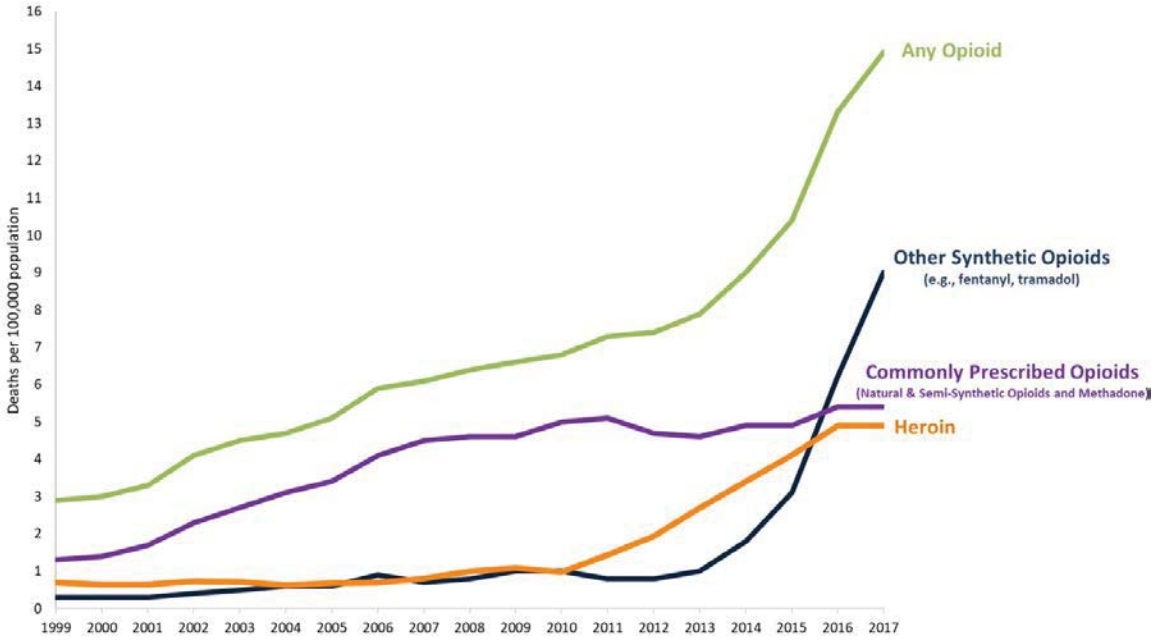
[21] GAO, *OxyContin Abuse and Diversion.*

[22] GAO reported that, according to Purdue Pharma, from April 2001 through May 2003 at least 10 Purdue employees were disciplined for using unapproved materials in promoting OxyContin. Disciplinary actions included warning letters, suspension without pay, and termination.

deaths from heroin has also risen sharply. As a result, while nearly 3 opioid overdose deaths occurred per 100,000 people in the year 2000, by 2017 that number had more than quadrupled to 15 opioid overdose deaths per 100,000 people.[23] Figure 2 outlines the rate of overdose deaths for various types of opioids from 2000 through 2017.

Figure 2

Overdose Deaths Involving Opioids, by Type of Opioid, United States 2000–2017



Source: CDC National Center for Health Statistics, National Vital Statistics System, "Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000–2017"

The Closed System of Distribution, Regulating Registrants, and Investigating the Diversion of Controlled Substances

Under the CSA, DEA is responsible for ensuring that all controlled substance transactions take place within a congressionally mandated closed system of distribution. The closed system of distribution regulates the flow of controlled substances from the different types of registrants, which include importers, manufacturers, distributors, practitioners, and dispensers. When controlled substance transactions fall outside the closed system of distribution, the activity constitutes diversion.

DEA's OD manages the Diversion Control Program to regulate the registrant population and investigate diversion matters. The Diversion Control Program has two major objectives with respect to practitioner-level diversion: (1) identify,

[23] CDC National Center for Health Statistics, National Vital Statistics System, "Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000–2017," www.cdc.gov/drugoverdose/images/data/OpioidDeathsByTypeUS.PNG (accessed September 25, 2019).

investigate, and prosecute violators that are operating in a manner that requires federal action and (2) assist the states with their regulatory responsibilities through active investigations and information sharing. Although these objectives address diversion at the practitioner level, OD initiates investigations resulting from complaints against registrants at every level, including manufacturers and distributors.[24]

DEA Oversight and Management of the National Diversion Control Program

DEA's United Nations Reporting and Quota Section, also referred to as the "Quota Section," sets the domestic quotas and international estimates for the manufacture, import, and export of controlled substances on Schedules I–IV and some List I chemicals.[25] Each calendar year, the Quota Section determines three types of pharmaceutical quotas for the basic classes of controlled substances and ensures that DEA is compliant with its diversion control responsibilities pursuant to United Nations treaties:

1. The APQ, or the national quota, in part comprises the total amount of the Individual Manufacturing Quotas issued to registered bulk manufacturers. The APQ is the maximum amount of each basic class of Schedule I and II controlled substances the DEA Administrator deems necessary for manufacture in a calendar year, by all pharmaceutical manufacturers combined, for the estimated medical, scientific, research, and industrial needs of the United States or for lawful export. DEA receives estimates from FDA for the amount of controlled substances that FDA believes should be manufactured during a calendar year. Once DEA considers FDA's viewpoint, the DEA Administrator sets the APQ.
2. The Individual Manufacturing Quota is the amount of a basic class of controlled substances the DEA Administrator allocates, in consultation with the Quota Section, to specific registered bulk manufacturers in order to manufacture the substance by producing, preparing, propagating, compounding, or processing it from another substance.
3. The DEA Administrator, in consultation with the Quota Section, sets the Procurement Quota to registered manufacturers that desire to obtain any Schedule I and/or II basic class of controlled substance in order to continue manufacturing that substance by packaging, repackaging, labeling, relabeling, or producing dosage forms or other substances.

[24] DEA Diversion Control Manual, October 2017, Section 5245.1, Introduction, 16.

[25] DEA, "Quotas," www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/dang_1.pdf#search=Quota (accessed June 28, 2018). See also DEA, "Drug Scheduling," www.dea.gov/drug-scheduling and "List I and List II Chemicals," www.deadiversion.usdoj.gov/chem_prog/34chems.htm (both accessed September 25, 2019).

Later in this report, we discuss how DEA set these quotas during the scope of our review.[26]

DEA also has Tactical Diversion Squads (TDS) to investigate registrants, particularly doctors and pharmacists, that divert controlled substances outside the scope of their professional medical practice.[27] These squads investigate criminal diversion cases with a nexus to prescription drugs that are diverted for profit.[28] A typical TDS consists of Diversion Investigators; Special Agents; Intelligence Analysts and, at times, other federal law enforcement professionals, who work alongside state and local Task Force Officers to investigate the diversion of controlled pharmaceuticals.

In addition, DEA Diversion Investigators enforce the CSA, the Chemical Diversion and Trafficking Act of 1987, and DEA regulations to ensure compliance by all current and prospective registrants.[29] Although some Diversion Investigators are assigned to a TDS exclusively, others focus primarily on conducting scheduled regulatory investigations based on a work plan established by DEA headquarters, which sets the cycle of regulatory inspections as well as investigations of registrants that are based upon complaints, discovery of noncompliance, or as part of criminal investigations brought to their attention. When the diversion unit of a DEA field division receives a tip, Diversion Investigators, whether or not they are assigned to a TDS group, may also conduct criminal investigations of registrants suspected of diverting pharmaceutical drugs for illicit use.

DEA's Office of Chief Counsel (CCD), Diversion & Regulatory Litigation Section, represents the government in all administrative hearings held by DEA's Office of Administrative Law Judges. In regulatory cases, CCD Attorneys litigate administrative actions against registrants (doctors, pharmacies, distributors, manufacturers, or anyone that holds a DEA registration to handle controlled

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[26] See 21 C.F.R. § 1303.11 (Aggregate Production Quota) and § 1303.13 (Procurement Quota) and 21 C.F.R. §§ 1303.21–1303.27 (Individual Manufacturing Quota).

[27] DEA, Press Release, "Announcement of New Tools to Address Opioid Crisis," November 29, 2017, www.dea.gov/pr/speeches-testimony/2017t/112917t.pdf (accessed September 25, 2019).

As of August 2017, DEA had established 77 TDS groups in 44 states.

[28] TDS members are authorized to work only on investigations that have a connection to prescription pills, such as OxyContin and hydrocodone. A TDS is not authorized to work on investigations that involve only non-pill related drugs, including heroin, or synthetic opioids, such as fentanyl, that were manufactured in other countries and smuggled into the United States. The proscription on TDS members' work is due to funding regulations that aim to preserve diversion funds exclusively for diversion activities.

[29] The Chemical Diversion and Trafficking Act of 1987 amended the CSA to establish recordkeeping and reporting requirements for the manufacture, distribution, importation, and exportation of listed precursor and essential chemicals. The Chemical Diversion and Trafficking Act prohibits the distribution of such chemicals unless the recipient provides a certification of lawful use and proper identification. See P.L. 100-690 and 21 U.S.C. §§ 801–971.

substances) that are potentially in violation of the CSA and DEA regulations.[30] Regulatory violations that warrant an administrative enforcement action, such as an Order to Show Cause (OTSC) or an Immediate Suspension Order (ISO), described in more detail below, are referred by Diversion Investigators to CCD for litigation. DEA uses OTSCs and ISOs to hold registrants accountable for violations, such as poor recordkeeping; inadequate security; practicing without a state medical license; and unlawfully prescribing any federally controlled substance, including a prescription opioid, outside the usual course of professional practice.[31]

In accordance with the Administrative Procedure Act of 1946, 5 U.S.C. § 551, DEA Administrative Law Judges (ALJ) conduct formal hearings in regulatory cases and provide a recommended decision in cases referred by Diversion Investigators to CCD as a result of a registrant's violations.[32] ALJs track the number of cases filed by CCD and report statistical information and significant trends to the DEA Administrator. In all regulatory cases in which an OTSC or an ISO is issued, the DEA Administrator makes the final agency decision.

DEA Registrant Databases and Reporting Systems

Following the enactment of the CSA in 1971, DEA began to systematically collect and maintain registrant records regarding production and ordering information, theft and loss, and suspicious orders.[33] Beginning in the late 1970s, pursuant to 21 C.F.R. § 1304.33, all manufacturers and distributors of select controlled substances were required to report their controlled substance activity to DEA using the Automated Reports and Consolidated Orders System (ARCOS). DEA developed ARCOS to monitor ordering information from manufacturers and distributors for Schedule I, Schedule II, and some Schedule III controlled substances.[34] Also, federal regulations require registrants to report drug theft or

[30] CCD exercises DEA's authority under 21 C.F.R. §§ 1301.31–46 and 1316.41–68, which establish procedures for DEA to revoke, deny, or suspend registrations and set a standard of imminent danger to the public health for issuing an Immediate Suspension Order (ISO). However, CCD does not decide whether administrative cases are viable. Rather, senior leadership of the Office of Chief Counsel makes decisions on whether and how to proceed in any administrative DEA case.

[31] When DEA issues an OTSC, the registrant is permitted to continue operations unless the registrant voluntarily surrenders its registration prior to an administrative hearing. If DEA issues an ISO, a registrant must immediately suspend operations until the case is resolved by an administrative hearing and a final decision is issued. A registrant subject to an ISO may also voluntarily surrender its registration.

[32] The Administrative Procedure Act of 1946 applies to all Executive Branch agencies, including some independent government agencies, and prescribes procedures for agency actions such as rulemaking, as well as standards for judicial review of agency actions.

[33] Effective May 1, 1971, the CSA, § 827 of the *U.S. Code,* required DEA to report controlled substance activity to the U.S. Attorney General.

[34] DEA, "ARCOS Reporting," www.deadiversion.usdoj.gov/arcos/index.html (accessed June 28, 2018). Most manufacturers and distributors must use ARCOS to report inventories, acquisitions, and dispositions of all controlled substances on Schedules I and II, as well as gamma-hydroxybutyric acid controlled substances on Schedule III.

loss to their local DEA field division in writing within 1 business day of discovering the loss.[35] The DEA Theft or Loss Reports System database houses these reports.[36]

Additionally, the Registrant Information Consolidated System (RICS), also known as "CSA II," is a database that consolidates several of DEA's internal systems, each with its own uniquely different functions, including Quota information, ARCOS, and providing access to registrant actions and other information. DEA uses RICS to manage all registrant records.[37]

Finally, in 2008 DEA developed the Suspicious Order Reporting System (SORS) to house reports that manufacturers and distributors of controlled substances are required by federal regulation to provide DEA when they detect suspicious orders, including those of unusual quantities or deviations from normal ordering practices. However, during the scope of our review, we found that the SORS database included reports from only 8 of the approximately 1,400 manufacturers and distributors of controlled substances. Each of those 8 manufacturers and distributors had provided their reports directly to DEA headquarters, while the remaining registrants reported suspicious orders to DEA field divisions.[38] We discuss these systems later in this report and in greater detail in Appendix 2.

Collaboration with State Partners and the Prescription Drug Monitoring Program

As indicated above, one of the objectives of DEA's Diversion Control Program is to assist the states, through active investigations and information sharing, with monitoring the prescribing and dispensing practices of practitioners to prevent diversion and prescription drug abuse.[39] According to DEA, its field divisions and headquarters communicate with state medical and pharmacy boards to share information about DEA regulations and registrant reporting requirements. DEA told OIG that it is through information sharing that it keeps state partners apprised of administrative enforcement actions, such as suspensions or revocations of DEA registrations.

While databases such as ARCOS capture ordering information reported to DEA from manufacturers and distributors of controlled substances, DEA does not have the ability to capture prescription information on doctors, dentists, pharmacies, and patients. Instead, Prescription Drug Monitoring Programs (PDMP) are state-run databases that capture this information through electronic monitoring.

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[35] 21 C.F.R. § 1301.76(b).

[36] DEA, "Report Theft or Loss of Controlled Substances," www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html (accessed September 25, 2019).

[37] DEA, "Privacy Impact Assessment for the Registrant Information Consolidated System," www.dea.gov/sites/default/files/2018-06/rics_%20pia_060414.pdf (accessed September 25, 2019).

[38] According to 21 C.F.R. § 1301.74(b), registrants "shall notify the local DEA field division when suspicious orders are discovered."

[39] DEA Diversion Manual, 5245.12, Objectives, 16.

According to DEA's 2017 National Drug Threat Assessment, as of April 2017 all 50 states and Guam have active PDMPs tracking in-state prescriptions and the District of Columbia has been given authorization to create a PDMP. The goal of the PDMP is to assist medical professionals in the identification and prevention of prescription drug abuse. Some Diversion Investigators and Special Agents work with their state partners to access data from the PDMP on an ad hoc basis because some states limit or prohibit federal law enforcement's access to this information.

Federal Interagency Coordination

According to DEA, DEA collaborates with HHS on some cases to obtain information related to doctors and pharmacies that participate in healthcare fraud. DEA told us that these types of investigations increasingly have ties to the diversion of controlled pharmaceuticals, including opioids. When registrants lose their eligibility to participate in federal programs such as the Medicare and Medicaid program due to involvement in healthcare fraud, DEA has the authority to revoke a registrant's DEA registration. (We further discuss DEA's collaboration with HHS later in the report.) DEA also works with the U.S. Postal Service to combat the illegal importation of controlled substances, including pharmaceutical opioids, through the mail and with the U.S. Department of Homeland Security to combat the smuggling of controlled substances through U.S. ports of entry, particularly along the Southwest border.[40] Finally, DEA works with the Office of National Drug Control Policy to draft guidance, in collaboration with all of the Executive Branch agencies, on a National Drug Control Strategy for illicit and pharmaceutical controlled substances.[41]

DEA Registrant Enforcement Process and Actions

In accordance with 21 U.S.C. §§ 824(c)(2)(A) and 824(d)(1), DEA uses administrative enforcement actions to suspend, revoke, or deny a DEA registration. DEA may issue a registrant an OTSC to explain the basis for DEA's initiation of administrative proceedings that may lead to revoking the registration.[42] Registrant violations that are more egregious in nature may require immediate action. In these cases, DEA will encourage the registrant to voluntarily surrender its registration. If the registrant does not, DEA will also issue an ISO against the registrant to immediately suspend the registration if there is evidence of "imminent danger to public health or safety."[43] If the violations do not warrant immediate

[40] OIG also reviewed cooperation between the Departments of Justice and Homeland Security in Southwest border criminal investigations. See DOJ OIG, *A Joint Review of Law Enforcement Cooperation on the Southwest Border between the Federal Bureau of Investigation and Homeland Security Investigations,* Evaluation and Inspections Report 19-03 (July 2019), www.oig.justice.gov/reports/2019/e1903.pdf (accessed September 10, 2019).

[41] Despite the ongoing national impact of the opioid epidemic, the Office of National Drug Control Policy did not publish the current National Drug Control Strategy until late January 2019.

[42] 21 U.S.C. § 824(c)(2)(A).

[43] 21 U.S.C. § 824(d)(1).

action, DEA will encourage the registrant to voluntarily surrender its registration or it may use an OTSC to initiate the revocation process.

In April 2016, Congress enacted the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, or the "Marino Bill," which created a new standard of proof necessary for DEA to issue an ISO. Pursuant to 21 U.S.C. § 824(d)(2), in order to issue an ISO against a registrant, DEA must prove that the registrant's conduct was an "imminent danger to the public health or safety" because the registrant failed to maintain effective controls against diversion, or to otherwise comply with the obligations of DEA registration, and there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance would occur unless there is an immediate suspension of the registration.[44]

A Letter of Admonition is an administrative enforcement action that DEA uses to bring a registrant into compliance for minor infractions, such as recordkeeping violations. In addition, DEA may use a Memorandum of Agreement (MOA) to establish a written contract between DEA and a registrant to resolve more severe violations, such as failing to report all suspicious orders. An MOA, typically issued in a case that has nationwide impact, establishes the basis for more severe administrative enforcement actions when violations persist.

Scope and Methodology of the OIG Review

This review examined DEA's regulatory activities and enforcement efforts to combat the diversion of opioids to unauthorized users. Specifically, we evaluated (1) DEA's enforcement regulations, policies, and procedures; (2) DEA's use of enforcement actions involving manufacturers, distributors, physicians, and pharmacists that violate these regulations, policies, and procedures; and (3) DEA's coordination with state and local partners to combat the opioid epidemic. Our fieldwork occurred from August 2017 through June 2018 and consisted of document review, data analysis, and interviews. We assessed DEA's enforcement efforts involving registrants that occurred from FY 2010 through FY 2017.

We conducted interviews with officials at DEA, U.S. Attorney's Offices, and the Office of the Deputy Attorney General. We also reviewed DEA policies and procedures and charging documents and conducted extensive analysis of DEA data. Additionally, we reviewed data related to all of DEA's opioid anti-diversion activities, including investigations opened and closed by OD; civil and criminal case filings against distributors, manufacturers, pharmacies, and doctors; Letters of Admonition, MOAs, ISOs, and OTSCs concerning registrants; voluntary registrant surrenders of DEA registration, including the number of such surrenders related to DEA enforcement actions; and actions brought against distributors and manufacturers. We also reviewed all fines that DEA levied against registrants, including the amount, date, and recipient of each fine. For more details about our scope and methodology, see Appendix 1.

[44] 21 U.S.C. §§ 823 and 824(d)(2).

RESULTS OF THE REVIEW

DEA Was Slow to Respond to the Dramatic Increase in Opioid Abuse and Needs to More Fully Utilize Its Regulatory Authorities and Enforcement Resources to Detect and Combat the Diversion of Controlled Substances

We found that DEA did not fully utilize its available regulatory authorities as part of its effort to combat the diversion of pharmaceutical opioids, even as the rate of opioid use and abuse in the United States increased dramatically from 1999 to 2017. Due mostly to opioid abuse, the rate of opioid overdose deaths in the United States grew, on average, by 8 percent per year from 1999 through 2013 and by 71 percent per year from 2013 through 2017.[45] Yet, from 2003 to 2013, DEA authorized manufacturers to produce substantial amounts of opioids.[46] For example, the Aggregate Production Quota (APQ) of oxycodone in the United States increased over 400 percent, from 34,482 kilograms in 2002 to a high of 153,750 kilograms in 2013. From 2014 to 2016, DEA slightly reduced the APQ for oxycodone, from the high of 153,750 kilograms in 2013 to 139,150 kilograms in 2016.[47]

However, it was not until 2017 that then acting DEA Administrator Chuck Rosenberg reduced the APQ for most controlled substances, including oxycodone, by 25 percent. Rosenberg approved a reduction in the APQ of oxycodone from 139,150 kilograms in 2016 to 101,500 kilograms in 2017. In 2018, DEA further reduced the APQ for oxycodone by 6 percent, to 95,692 kilograms. See Figure 3 below for the historical trends in APQs for oxycodone.

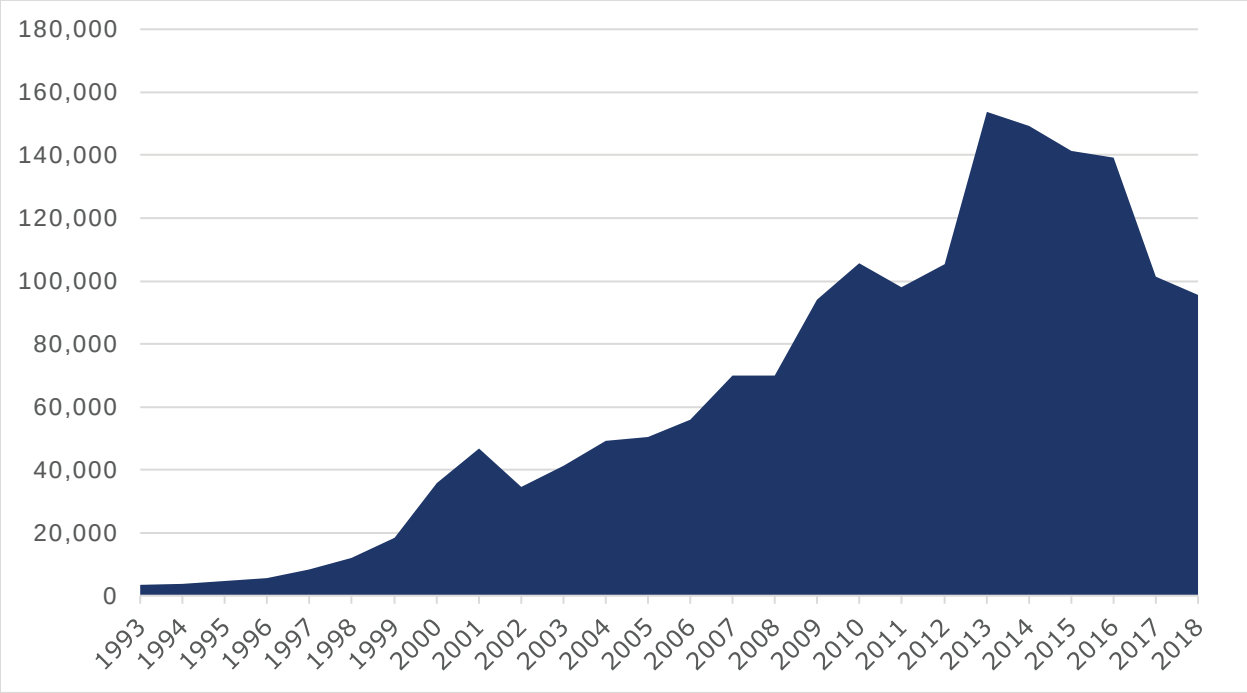
[45] Centers for Disease Control and Prevention, "Drug Overdose Deaths in the United States, 1999–2017," www.cdc.gov/nchs/products/databriefs/db329.htm (accessed September 25, 2019).

[46] As discussed in the Introduction, DEA approves the amount of the basic class of controlled substances that individual pharmaceutical manufacturers can produce each year, which is known as the Individual Manufacturing Quota. The Aggregate Production Quota (APQ) is the total combined amount of quotas set by the DEA for all manufacturers producing basic classes of controlled substances. The Controlled Substances Act of 1970 requires DEA to establish aggregate production quotas by July 1 of the year preceding the year to which the quota applies. For example, for quota year 2015 the proposed notice was published on July 2, 2014. See 21 C.F.R. § 1303.21.

[47] The APQ for oxycodone was 149,375 kilograms in 2014; 141,375 kilograms in 2015; and 139,150 kilograms in 2016.

Figure 3

Aggregate Quota Production for Oxycodone (in Kilograms of Anhydrous Base)



Source: OIG analysis of DEA data

In March 2018, then Attorney General Jeff Sessions directed DEA "to evaluate and consider whether or not to amend its regulations governing the aggregate production quota."[48] At the time, DEA's regulations already contained a catch-all provision that enabled the DEA Administrator to consider "any relevant factor" in making quota decisions. Pursuant to those existing regulations, then acting Administrator Rosenberg ordered a substantial reduction in the 2017 APQ for opioids and other controlled substances, as noted above. In response to Sessions' direction, DEA proposed a regulation that explicitly detailed the additional factors, including the diversion of pharmaceutical opioids and the opioid epidemic, that DEA can consider in setting quotas.[49]

[48] DOJ, Press Release No. 18-255, "Attorney General Sessions Takes Further Action to Combat Opioid Crisis—Directs the DEA to Evaluate Aggregate Production Quotas," March 1, 2018, www.justice.gov/opa/pr/attorney-general-sessions-takes-further-action-combat-opioid-crisis-directs-dea-evaluate (accessed September 25, 2019).

[49] Proposed Rules, 21 C.F.R. Part 1303, Docket No. DEA–480, RIN 1117–AB48, Controlled Substance Quotas, 83 Fed. Reg. 76,17329 (Apr. 19, 2018), www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0419.htm (accessed June 28, 2018). On July 16, 2018, the proposed rule became final, and it became effective on August 15, 2018. See Final Rule, 21 C.F.R. Part 1303, Docket No. DEA–480, RIN 1117–AB48, Controlled Substance Quotas, 83 Fed. Reg. 136,32784 (Jul. 16, 2018).

DEA's Administrative Enforcement Actions Have Not Been Fully Effective in Detecting and Combating the Diversion of Opioids and Other Controlled Substances

We identified other areas in which DEA's regulatory and enforcement efforts could have been more effective in combating opioid diversion. First, DEA's preregistration process did not adequately vet all new applicants before granting DEA registration.[50] Second, DEA policy allowed, and still allows, registrants that have had their registration revoked, or that have surrendered it, to reapply for registration the day after a revocation is enforced or a surrender occurs.[51] Third, in 2010, DEA gave practitioners the option to use electronic prescriptions instead of paper prescriptions to keep pace with technology and combat prescription fraud. However, despite the rampant use of paper prescriptions to divert pharmaceutical opioids, DEA took no additional steps to further revise its regulations to require that all prescriptions be electronic, considering the opioid crisis.[52] Fourth, DEA headquarters had stringent requirements for field divisions to complete their annual Diversion Control work plans, which left little room for targeting registrants suspected of diversion.[53] Finally, beginning in 2013, DEA rarely used its strongest enforcement tool, the Immediate Suspension Order (ISO), to stop registrants from diverting prescription drugs, and DEA continues to experience challenges in rendering final decisions on administrative actions in a timely manner.

Preregistration Investigations Did Not Adequately Vet Applicants

The Controlled Substances Act of 1970 (CSA) requires that each person or firm that proposes to handle controlled substances or List I chemicals obtain a DEA registration unless exempted.[54] The purpose of a preregistration investigation is to determine the fitness and suitability of the applicant to engage in the activities for which registration is requested and to ensure that the applicant is familiar with its responsibilities to prevent diversion. However, we found that DEA's preregistration process did not appropriately safeguard against the diversion of pharmaceutical opioids, or any other drug, because DEA did not conduct background checks on all new applicants and relied instead on the good faith of applicants to disclose relevant information, even in cases in which the applicant had previously engaged in criminal activity.

According to the Associate Section Chief of DEA's Regulatory Section, DEA conducts preregistration inspections only on "Type B" registrants, which includes manufacturers, distributors, exporters, importers, narcotic treatment programs, and applicants whose registration previously had been suspended or revoked. Therefore, "Type A" registrants, which include physicians, dentists, and

[50] DEA Diversion Control Manual, October 2017, Sections 5221.1, 5221.3, and 5222.1.

[51] 21 C.F.R. § 1301.13.

[52] 21 C.F.R. § 1304.04(h)(4).

[53] DEA Diversion Control Manual, Sections 5231.11 and 5231.12.

[54] According to DEA's Diversion Control Manual, applicants can receive exemption from DEA registration under 21 U.S.C. § 822(c) or 21 C.F.R. §§ 1301.23–1301.27, 1309.25, or 1309.26.

pharmacists, are rarely required to undergo a preregistration investigation. We also found that only two DEA field divisions routinely conducted preregistration investigations on pharmacy applicants. All other field divisions issued a registration if a pharmacy applicant had a valid state license.

During interviews, some field division staff expressed concerns about the lack of vetting of physicians and pharmacies during the preregistration process. One Diversion Program Manager (DPM) told us that if a pharmacy owned by a corporation is sold to another corporation, the new corporation could circumvent the preregistration process and DEA would have no knowledge of any conduct inconsistent with holding a DEA registration. The new corporation could assume the previous corporation's registration and order as much oxycodone or any other controlled substance as desired without obtaining a new DEA registration.[55] Another DPM told us that, due to local issues with some pharmacy applicants, routine preregistration checks would be helpful. However, the DPM also told us that in general practice such checks are discouraged because DPMs are directed to do their work only within the annual Diversion Control work plan.

Further, we found that if a potential registrant does not disclose past criminal history, suspensions, revocations, or other unbecoming conduct, DEA does not inquire further. During interviews, several Diversion Investigators told us that, if an applicant with a valid state license does not answer "yes" to the registrant application's liability questions (as to whether the applicant has had issues with previous state licenses or allegations of misconduct), DEA approves the application without further verification from the state medical and pharmacy boards. As a result, an applicant that falsifies answers on the application could fraudulently obtain a DEA registration. The Associate Section Chief of the Regulatory Section told us that with 1.7 million registrants there is no way for DEA to know whether applicants are being untruthful unless DEA is already aware of disqualifying information. Indeed, one Diversion Investigator told us that, even if an applicant answered answers "yes" to one or more of the liability questions, some of her colleagues do not follow up to determine whether the applicant should be denied a DEA registration.

In response to a working draft of this report, DEA provided a copy of its policy prohibiting DEA Diversion Control staff from using the Federal Bureau of Investigation's National Crime Information Center (NCIC) database to perform criminal background checks on registrants' employees, as well as DEA's own Narcotics and Dangerous Drugs Information System (NADDIS), which captures

[55] See 21 C.F.R. § 1301.52. According to DEA's Registration Section, if a registrant is incorporated or is a limited liability company it is considered a legal entity. If someone buys the legal entity in its entirety and the legal entity has not ceased to exist, in effect nothing has changed and DEA does not need to be notified.

information collected during DEA investigations generally.[56] According to DEA, Diversion Control staff rely on information obtained from a privately run proprietary database to conduct background checks on registrants' employees, which limits the staff's ability to conduct criminal background checks during the preregistration process.

DEA's preregistration investigations are an important tool for vetting applicants to ensure that they are suitable candidates for handling controlled substances. While we are not questioning the validity of state medical and pharmacy board investigations, we believe that DEA's failure to conduct preregistration investigations on all applicants, including pharmacies, creates the risk that DEA would be unaware that some of these registrants may have engaged in conduct or criminal activity that would render them unfit to obtain a DEA registration.

The Impact of Revoking a Registration Is Limited because Registrants Can Reapply for Registration Immediately Following Revocation

We found that registrants that have had their registration revoked, or that have surrendered it, can reapply for registration the day after the enforcement action or surrender occurs.[57] As a result, registrants that potentially pose a significant risk of diverting pharmaceutical opioids may be given the opportunity to do so once again. Moreover, as one DEA Chief Counsel Attorney told us, when a registrant reapplies the Diversion Investigator is required to reinvestigate the applicant because the burden is on DEA to prove that the former registrant should not receive a new DEA registration. In addition, under the CSA, a registrant must be issued an Order to Show Cause (OTSC) and provided the opportunity to be heard by a DEA Administrative Law Judge (ALJ) before DEA can deny the registrant's application.[58]

Several Diversion Control staff also told us that, typically, if a revoked registrant immediately reapplies for a registration, staff will request an OTSC to prevent the registrant from receiving a new registration. However, a DEA Chief

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[56] Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA, Policy Regarding the Use of NADDIS and NCIC for Criminal History Checks for DEA Registrants, DFN: 060-01, April 25, 2011.

NCIC is a computerized index of criminal justice information (i.e., criminal record history information, fugitives, stolen properties, missing persons) that is available to federal, state, and local law enforcement and other criminal justice agencies to provide ready access to information from other criminal justice agencies. The information is used in apprehending fugitives, locating missing persons, locating and returning stolen property, as well as in the protection of the law enforcement officers encountering the individuals described in the system.

NADDIS is a computerized database containing information regarding DEA narcotics investigations that is used across DEA field divisions.

[57] 21 C.F.R. § 1301.13.

[58] 21 U.S.C. §§ 824(c)(1) and (2). The statute and its implementing regulations, 21 C.F.R. §§ 1300, et seq., are silent with respect to circumstances wherein a registration is previously revoked or surrendered for cause and the registrant immediately reapplies for DEA registration.

Counsel Attorney told us that there are cases in which an OTSC was not issued and a new DEA registration was granted even though the registrant had prior violations. He said that in one case the field division was simply "worn out" because it had spent years putting together the original revocation case. Once the registrant reapplied, the field division considered pursuing a Memorandum of Agreement (MOA), which is a less stringent enforcement tool than an OTSC. He explained that these cases were the hardest for him because the field division and DEA's Office of Chief Counsel (CCD), Diversion & Regulatory Litigation Section, was aware of the registrant's history of diversion yet the regulations permitted the registrant to obtain a new registration.

In another example, also provided by a Chief Counsel Attorney, a doctor, who had engaged in serious misconduct and had his registration revoked, moved to another state under the authority of a different DEA field division and immediately reapplied for and was granted a new DEA registration, even though the field division that revoked the previous registration expressed concerns. The same attorney stated that renewing the doctor's registration was "a terrible mistake" and that such cases really "defang" diversion control. (See the text box for an example of a registration that was reinstated under similar circumstances.)

Reinstatement of Registrant Dentist with a History of Substance Abuse and a Criminal Record

We learned that DEA reinstated the registration of a dentist who had voluntarily surrendered his medical license and DEA registration on two separate occasions. The dentist had a 25-year history of substance abuse and had had interactions with federal and state law enforcement. The dentist allegedly bought a firearm from an undercover police officer after having been convicted of a felony and allegedly purchased cocaine and heroin during the course of an unrelated investigation. The dentist also failed an initial drug test, having tested positive for marijuana.

In light of this information, the DEA Diversion Investigator requested that an OTSC be issued to prevent the approval of the dentist's reapplication. However, according to the Diversion Investigator, DEA's CCD declined to issue an OTSC because the dentist's transgressions were over 5 years old. Instead, DEA entered into an MOA with the dentist, which enabled him to obtain another DEA registration.

Source: OIG analysis

We believe that registrants who reapply for registration immediately after revocation or surrender may pose a heightened risk to public safety and that, therefore, it is in the public's interest for DEA to ensure that those registrants' reapplications receive heightened scrutiny.[59] In view of our finding that DEA has granted applications for registration after the applicants' DEA registration had been recently revoked or surrendered, DEA should take steps to (1) ensure that DEA Diversion Control staff responsible for adjudicating registrant reapplications are fully informed of the applicants' prior history and (2) improve information provided to staff about the standards to apply in making decisions on such applications. These steps should be designed to

[59] 21 U.S.C. §§ 824(a)(1–5) of the CSA outline the factors considered when determining whether a DEA registration should be suspended or revoked. Specifically, 21 U.S.C. § 824(a)(4) states that DEA considers acts committed by a registrant that are "inconsistent with the public interest" as grounds for suspension or revocation of a DEA registration.

provide DEA Diversion Control staff a sufficient basis, consistent with law, to deny registration to such applicants absent changed circumstances and could include:

- enhancing existing guidance and training and developing guidance for DEA Diversion Control staff on the factors that should be considered in determining whether to grant such applications, including changed circumstances and passage of time;
- ensuring that all Diversion Control staff have access to information through a national database relating to registrants that have been subject to prior revocations, surrenders, or loss of state medical licenses;
- requiring that Diversion Control staff provide a written explanation describing the change of circumstances if their decision is to grant a registration to an applicant whose registration had previously been revoked or surrendered or whose state medical license had been revoked; and
- considering revisions to DEA's registration form to gather additional information relevant to the decision from applicants.

DEA Does Not Mandate Electronic Prescriptions for Controlled Substances

Various DEA staff told us that paper prescriptions are far less secure and are more susceptible to prescription fraud, a pervasive issue throughout the country that has led to opioid diversion. We found that in 2010 DEA revised its regulations to allow practitioners to issue electronic prescriptions to combat prescription fraud.[60] However, DEA did not mandate electronic prescriptions for all DEA registrants. Former acting DEA Administrator Robert Patterson told us that DEA has not mandated that all registrants issue electronic prescriptions because some smaller pharmacies could not meet the computer requirements for electronic prescriptions.

Diversion Control staff described to us "prescription rings" that involve street-level dealers working alongside medical professionals and "runners" fraudulently obtaining paper prescriptions and filling them at local pharmacies. We learned that, in an effort to prevent prescription fraud, several states, such as Connecticut, New York, Massachusetts, Minnesota, and Maine, have passed legislation mandating electronic prescribing and that California, Missouri, Vermont, Texas, and Ohio are considering similar legislation. In light of the pervasive nature of prescription fraud, and given that several states already mandate electronic prescriptions, DEA should consider changing its regulations to assist in preventing prescription fraud and to enable DEA to focus on other forms of diversion.

[60] Interim Rule, 21 C.F.R. Parts 1300, 1304, 1306, and 1311, Docket No. DEA–218, RIN 1117–AA61, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16,236 (Mar. 31, 2010), as codified in 21 C.F.R. § 1306.08, Electronic Prescriptions, and 21 C.F.R. § 1304.06, Records and reports for electronic prescriptions.

DEA's Work Plan Requirements Hinder Diversion Investigators' Ability to Inspect Registrants That Are Most Likely Involved in Diversion

We found that DEA headquarters has stringent requirements for Diversion Control work plans. The work plans detail the type of registrants that field divisions must investigate each year, and Diversion Investigators must complete the investigations within specific timeframes. We also found that field divisions are evaluated based on whether they complete their work plans, which leaves little room for quickly responding to new information targeting local registrants suspected of prescribing or dispensing opioids outside the scope of legitimate medical practice.

According to DEA's Diversion Control Manual, the Office of Diversion Control (OD) develops Diversion Control work plans for the field divisions. The work plans provide a schedule for conducting on-site investigations of non-practitioners to ensure their compliance with the CSA and continued eligibility for DEA registration. Diversion Control work plans require Diversion Investigators to conduct three levels of scheduled investigations: (1) primary/full investigations every 3 to 5 years, (2) secondary/follow-up investigations within 1 year of an administrative action, and (3) new registrant investigations no later than 1 year from a registrant's initial registration. The manual further states that the priority for the Scheduled Investigations Program is considered obligatory.

Diversion Control staff in DEA field divisions voiced concerns regarding the obligations of their work plan. For example, a DPM told us that her field division implemented an operation from 2013 through 2016 to eradicate pharmacies that were dispensing a large amounts of pills in that region. Through this initiative, her office's Diversion Control group secured 134 voluntary registration surrenders and issued 24 OTSCs to pharmacies. However, the operation was not in the field division's work plan and the DPM told us that, despite the impact of the group's actions, she felt that her field division leadership did not "appreciate" the group's targeted approach and just wanted the work plan completed. A Diversion Investigator told us of his frustration that following the work plan requires Diversion Investigators to inspect the same registrants over and over since there were no requirements for how often a registrant must be inspected.[61]

Former acting DEA Administrator Patterson acknowledged the constraints of Diversion Control work plans, which limit the field divisions' input on prioritizing investigations based on local issues. He understood that some Diversion Control staff in the field were frustrated over their lack of input. He told us that, from a

[61] To ensure compliance with the CSA and a registrant's eligibility for continued registration with DEA, the Diversion Control Manual requires DEA to conduct periodic on-site investigations of all controlled substance manufacturers; distributors; reverse distributors; importers; exporters; narcotic treatment programs; and Drug Abuse Treatment Act of 2000 waived physicians, also known as DATA waived physicians. DATA waived physicians are permitted to treat narcotic dependence with Schedule III–V narcotic controlled substances. The manual requires these registrants to be reinvestigated at least once every 3 years, with the exception of DATA waived physicians, who are reinvestigated once every 5 years.

Special Agent in Charge's perspective, working solely on the items in the work plan is too rigid and "not the way it needs to be," especially given the opioid epidemic. Patterson said that a working group was attempting to create more flexibilities in the work plans.[62] Further, an Assistant Special Agent in Charge expressed concerns about how the work plan affects employees' work ethic. He stated that, because the division's work plan sets inspection requirements at the beginning of the year, some Diversion Investigators end up investigating only what is required of them. OIG believes that, if true, this may result in missed opportunities to identify and detect serious diversion.

We believe that it is important for DEA to allow for flexibilities in Diversion Control work plans so that Diversion Investigators can balance the need to target noncompliant registrants that may be diverting pharmaceutical opioids and other dangerous drugs with the need to conduct routine investigations.[63]

DEA Rarely Used Its Strongest Enforcement Tool, the ISO, to Stop Registrants That Were Diverting Opioids and Other Prescription Drugs

We found that DEA's use of the ISO, its strongest enforcement tool, significantly decreased from FY 2011 through FY 2015, and again in FY 2017, as compared to prior years. Under the CSA, if a registrant's violation poses an "imminent threat" to public health or safety, DEA may issue an ISO, which immediately deprives the registrant of the right to manufacture, distribute, prescribe, or dispense controlled substances.[64] If a registrant or applicant violates the law but the threat is not imminent, DEA may issue an OTSC to the registrant, which must then prove why its registration should not be revoked, suspended, or denied.

We found that DEA reduced its use of ISOs by over 80 percent (38 to 6) between FYs 2010 and 2017, including by nearly 70 percent (45 to 14) in FY 2013 alone. Even prior to our review period, there was a 42 percent decrease (24 to 14) in ISOs issued between FYs 2008 and 2013. In fact, DEA issued more ISOs in

[62] In November 2015, the DEA Diversion Control Division formed a Field Advisory Committee, composed of five DPMs and four Assistant Special Agents in Charge, to facilitate communication between DEA field divisions and headquarters by providing a platform for input, discussion, and prioritization regarding issues facing the Diversion Control Program. In the spring of 2017, a working group began reviewing DEA's Diversion Control investigation work plans for the various field divisions and provided recommendations to the OD to modify them for FY 2019.

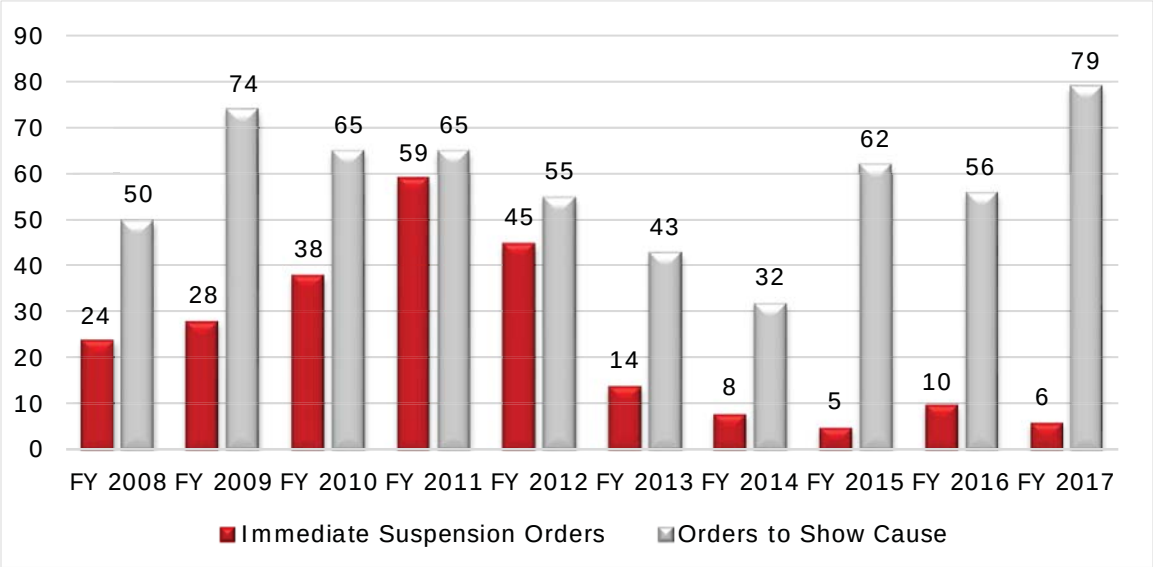
[63] In response to a working draft of this report, DEA provided the OIG with DEA's September 2018 policy, which modifies and provides greater flexibilities in the FY 2019 field division scheduled work plans to allow Diversion Control staff to better respond to the opioid epidemic. John Martin, Assistant Administrator, Diversion Control Division, DEA, Modification of the Controlled Substance and Chemical Regulatory Work Plan, DFN: 630-15, September 7, 2018.

[64] 21 U.S.C. §§ 823 and 824. In April 2016, Congress passed legislation that included a definition of "imminent danger" that raised the standard of proof necessary for DEA to issue an ISO. We discuss this change in greater detail below.

FY 2012 than FYs 2013–2017 combined.[65] By comparison, since FY 2014 the number of OTSCs issued by DEA has generally increased. See Figure 4.

Figure 4

ISOs and OTSCs Issued by DEA, FYs 2008–2017



Source: OIG analysis of DEA documents

We sought to determine the basis for the significant decrease between FY 2011 and FY 2017 in DEA's use of the one administrative tool that can immediately stop a registrant from diverting controlled substances. We were told about several factors that may have affected DEA's use of ISOs during this time period.[66] For example, the CCD Section Chief for the Diversion & Regulatory Litigation Section referenced a temporary restraining order issued by a U.S. District Court Judge in Washington, D.C., on February 3, 2012, that initially prevented DEA from enforcing an ISO against Cardinal Health, Inc.[67] The U.S. District Court Judge

[65] The data we used to determine the number of ISOs and OTSCs that were issued in FYs 2008–2009 was derived from our previous report, *Review of the Drug Enforcement Administration's Adjudication of Registrant Actions*, Evaluation and Inspections (E&I) Report I-2014-003 (May 2014), www.oig.justice.gov/reports/2014/e1403.pdf (accessed September 25, 2019). See Appendix 3 for information on prior work related to DEA diversion control efforts.

[66] In response to a working draft of this report, DEA acknowledged additional factors that it believed had contributed to the decrease in ISOs during our scope. Specifically, DEA noted that prescriptions declined nationwide, in many cases administrative enforcement actions were taken that did not result in ISOs, DEA did not pursue ISOs against registrants when it conflicted with an ongoing U.S. Attorney's Office (USAO) criminal investigation, Diversion Control staff had been insufficiently trained regarding administrative diversion remedies, and registration surrenders increased during the first few years of our scope.

[67] At the time of the Cardinal Health case, the CCD Section Chief for the Diversion & Regulatory Litigation Section worked as a DOJ Civil Division attorney and was defending the case on behalf of the U.S. government. According to Department protocol, if a registrant appeals an ISO in federal court, the government's case is defended by either the Department's Narcotics and Dangerous Drug Section or its Civil Division. Later in 2012, this official joined DEA as the CCD Section Chief for the Diversion & Regulatory Litigation Section.

granted the temporary restraining order because he could not determine how Cardinal Health posed an imminent threat to the community based on the evidence presented by the government. On February 29, the court held a preliminary injunction hearing and the government presented additional evidence demonstrating why an ISO against Cardinal Health was warranted. After learning the full extent of the government's evidence, some of which was not presented initially, the court ruled in the government's favor and allowed DEA to enforce the ISO against Cardinal Health.

However, in doing so, the CCD Section Chief told us that the U.S. District Court Judge was critical of DEA's evidentiary presentations in a number of cases. Specifically, according to the CCD Section Chief, the judge stated that, if DEA had presented all of its evidence against Cardinal Health initially, he never would have granted the temporary restraining order in Cardinal Health's favor. Further, in talking with colleagues regarding DEA cases, the court believed that "DEA is cutting corners" and "is not doing a good enough job with its evidentiary presentations and [DEA] needs to do better." The DPM with direct involvement in this case also told us that she recalled the judge advising DEA to include more evidence in its ISOs because DEA cannot shut down a business without telling the registrant why. After this case, the DPM said that DEA's use of ISOs started to "slow down." The CCD Section Chief told us that he keeps the court's feedback in mind moving forward as he wants every case to be able to stand up in court.[68]

Additionally, a former DEA Assistant Administrator, who led the OD from August 2015 to June 2017, advised us that an unusually high volume of ISOs from FY 2010 through FY 2012 resulted from DEA's Operation Pill Nation I (2011) and Operation Pill Nation II (2012) investigations in Florida. Collectively, Operations Pill Nation I and II resulted in ISOs against 63 DEA registrations. Thus, according to the former Assistant Administrator, the reduction in ISOs appears more pronounced from FY 2013 onward because those operations ended in FY 2012.[69] See the text box below for information regarding the effect of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (the "Marino Bill") on DEA's use of ISOs.

[68] The CCD Section Chief also stated that, based on his discussions with DEA leadership, between 2011 and 2012 DEA made a strategic decision "to go after" pharmaceutical suppliers such as distributors and pharmacies. In doing so, he acknowledged that these cases were more resource intensive and complicated and that the number of cases made against physicians would decline.

[69] Based on our analysis of DEA charging documents, we found that 46 percent (65 out of 142) of all ISOs between FY 2010 and FY 2012 were issued throughout the state of Florida. We believe that these ISOs were largely the result of DEA's Operations Pill Nation I and II, which combined led to 118 arrests, the surrender of more than 80 DEA registrations, the seizure of more than $19 million in assets, and the closure of at least 40 pain clinics. While we recognize that the high volume of ISOs in Florida may partly explain the sharp decrease we found since FY 2012, DEA issued only one ISO in Florida between FY 2013 and FY 2017. The CCD Section Chief for the Diversion & Regulatory Litigation Section acknowledged that this seemed low but said that the field did not refer cases to CCD that warranted more ISOs in Florida.

Finally, we found that the Diversion Control and CCD staffs had a poor working relationship, which sometimes hindered diversion investigations and the issuance of ISOs. Former acting DEA Administrator Patterson characterized the relationship between field division Diversion Control staff, OD, and CCD as historically "toxic." As one example of the issues between CCD and Diversion Control staff in the field, a DEA Special Agent told us about, and CCD acknowledged, problems during the investigation of an oxycodone and hydrocodone "pill mill" case in September 2016 that delayed the resolution of this case for over a year. The delay was particularly of concern because the doctor was allegedly linked to multiple individuals who fatally overdosed from the drugs he prescribed. After the Special Agent requested information from the initial CCD attorney, the attorney described his interaction with the Special Agent in an email exchange with the CCD Section Chief for the Diversion & Regulatory Litigation Section:

> [Special Agent] called me. He was really pissed, telling me not to talk to the [Assistant U.S. Attorney (AUSA)], demanding my work product on the case, etc. I basically lost it with him, explained (to the extent I was able) why it is problematic to proceed administratively, told him [not] to ask you for my work product (as I don't [think] that is appropriate under these circumstances). I also told him to lose the attitude, and to act more professionally.

In interviews, the Special Agent told us that CCD repeatedly had asked him to submit and resubmit investigative materials because CCD had misplaced them, which caused delays. It was not until a new CCD attorney was assigned months later that the case moved forward and DEA issued an OTSC against the doctor. Although the CCD Section Chief acknowledged the communication issues between the initial attorney and the Special Agent, he told us that a parallel U.S. Attorney's

Effect of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 on DEA's Use of ISOs

During the course of our review, we also considered the passage of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (Act) and its effect on DEA's use of ISOs. The Act's definition of imminent danger to the public health or safety required DEA to meet a higher standard of proof before issuing an ISO. While we were told that the new proof standard could negatively affect DEA's future ability to use ISOs effectively, we found, as shown in Figure 4, that DEA's use of ISOs had already decreased sharply in the years prior to the bill's passage. Given that the bill did not become law until April 2016, there was not yet sufficient data available during our fieldwork to assess the legislation's actual impact on DEA's ability to use ISOs.

Former acting DEA Administrator Patterson told us that he believed the only challenge the Act presented to DEA was that it required Diversion Investigators to be diligent about providing evidence to CCD attorneys as soon as they received it in order to satisfy the bill's imminent threat standard. Patterson stated that, if an alleged harm occurred a year before the investigator presented the case to the Chief Counsel, the imminent threat standard could not be met and the investigator would have to pursue another course of action, such as an OTSC.

Sources: OIG analysis and interviews

Office (USAO) investigation and expert witness issues also may have caused delays.[70]

In another example, Diversion Control staff expressed concerns to us that CCD did not take swift and aggressive action to issue an ISO in a particularly egregious case involving criminal conduct. Staff told us about a March 2015 request to CCD by a Tactical Diversion Squad (TDS) for an ISO against a California doctor. The TDS had obtained pictures and text messages showing that in exchange for opioid pharmaceuticals the then 62-year-old doctor was having sex with three patients, all of whom were addicts between the ages of 20 and 25. Diversion Control staff told us that CCD did not authorize the ISO. When we asked CCD about the case, CCD stated that in May 2015 it emailed TDS investigators a case file analysis describing the concerns it had and providing guidance about the evidence it would need to prove improper prescribing practices. Specifically, CCD told us:

> Although the allegations of improper prescribing were deeply troubling, the case file lacked essential evidence needed to proceed forward with an administrative case. Among other concerns, the case file lacked any of the prescriptions that DEA maintained that [the doctor] issued improperly, as well as the patient files corresponding to those prescriptions.

CCD responded to the TDS that once all the identified issues were addressed CCD would pursue an administrative enforcement action.[71] After receiving CCD's assessment, which the TDS Group Supervisor said he perceived as CCD "slamm[ing] the case," he instead referred the case to the USAO, which later indicted the doctor. The doctor pled guilty and is serving a 30-month prison sentence.

These examples illustrate a poor working relationship between the Diversion Control and CCD staffs. As a result of the difficulties that Diversion Control and CCD staffs had working together, CCD attorneys and numerous headquarters and field division Diversion Control staff told us that there was a reluctance on the part of the field to bring cases, particularly ISO referrals, to CCD.

We note that DEA has recently implemented a number of reforms to improve the working relationship between the Diversion Control and CCD staffs. In 2016 DEA implemented a new enforcement action intake process, which includes a conference call with CCD, the DEA Pharmaceutical Investigations Section, and field

[70] The CCD Section Chief for the Diversion & Regulatory Litigation Section said that DEA was not allowed to use the USAO's medical expert, who concluded that the doctor had issued prescriptions outside the course of legitimate medical practice. The CCD Section Chief also told us that another medical expert whom DEA was allowed to use did not reach the same conclusion.

[71] According to CCD, while the Diversion Control Unit Chief responded that he would consult with investigators about how to proceed, CCD officials stated that CCD "heard nothing further from either Diversion Control or San Diego [Field Division] on this matter for approximately 14 months." CCD told us that an OTSC against the doctor was issued on September 27, 2016. In November 2016, the doctor waived his right to a hearing on the OTSC and surrendered his DEA registration.

division Diversion Control staff, so that all parties can offer input and feedback on new cases.[72] DEA also co-located the Pharmaceutical Investigations Section and CCD to facilitate a more collaborative working relationship. Finally, CCD assigned attorneys to work with specific field divisions to improve relationships with field division Diversion Control staff.

Timeliness on the Part of the DEA Administrator Plays a Crucial Role in DEA Administrative Enforcement Actions

DEA's regulatory process provides that the DEA Administrator is the final decision maker in an administrative enforcement action. We found that in prior years a lack of timeliness significantly delayed revocations.[73] Based on our review of OTSCs, we determined that from FY 2010 through FY 2017, on average, the former acting DEA Administrator took nearly 10 months (302 days), and in a few cases approximately 2 years, to render a final decision after an ALJ issued a recommendation. However, we also observed that the DEA Administrator's timeliness in issuing final decisions showed signs of improvement during the scope of our review, decreasing from an average of 440 days in FY 2011 to an average of 103 days in FY 2017.[74] Nonetheless, this

DEA Did Not Consistently Meet Its Timeliness Guidelines

In 2014, DEA established timeliness guidelines for adjudicating OTSCs. The new guidelines generally provided the Office of the Administrator 180 days to issue a final decision after receiving the ALJ's recommendation. In addition, DEA's guidelines altered the timeline for the entire administrative process for OTSCs to 360 days. Despite the establishment of these guidelines, we found that, following their implementation, 25 percent (27 out of 110 cases) of all OTSCs that culminated in a final decision from the DEA Administrator did not meet the timeliness guidelines. We also found that on average five of these cases took the Administrator 13 months (390 days) to issue a final decision after the ALJ's recommendation.

Although we found indications that DEA has improved its timeliness in adjudicating OTSCs, we believe that additional improvement is necessary, given that registrants subject to an OTSC may continue to divert pharmaceutical opioids and endanger the community until the Administrator renders a final decision.

Source: OIG analysis of DEA documents

[72] Under the previous process, the OD and CCD evaluated administrative referrals from the field.

The administrative referral process begins when DEA issues an OTSC or an ISO to suspend or revoke a registration. According to 21 C.F.R. § 1301.43(a), a hearing with an ALJ takes place only if the registrant files a formal request within 30 days of being issued the OTSC or ISO. After pre-hearing statements and conferences are held with both DEA and the registrant, an administrative hearing occurs. Following the deadline for filing post-hearing briefs, the ALJ issues a recommended decision, which is forwarded to DEA's Office of the Administrator for final review. The DEA Administrator issues a final decision by adopting, modifying, or rejecting the ALJ's recommended decision.

[73] Although we reviewed DEA Administrator decisions for every ISO and OTSC that DEA issued during the scope of our review, our analysis includes only those 70 cases in which the date of the ALJ's recommendation was provided for an OTSC.

[74] Our analysis excluded cases that had not received a final decision from the DEA Administrator as of the end of FY 2017. Although our analysis appears to indicate that DEA improved its timeliness, we recognize that the results for the later years of our scope may be skewed because pending cases, which may linger for years, were not included in our analysis. For example, the sample size for our analysis for FY 2017 was limited to 4 cases, compared to 20 cases for FY 2011.

continuing failure to render a timely final decision is particularly concerning as registrants may continue to do business and potentially divert pharmaceutical opioids until DEA revokes their registrations.

DEA's inability to adjudicate enforcement actions in a timely manner is a challenge that has persisted for several years. OIG first identified this issue in our May 2014 report on DEA's adjudication of registrant actions, in which we found that, with the exception of ISOs, DEA generally did not have timeliness standards in place for the adjudication of registrant actions. In response to recommendations made in our 2014 report, DEA established timeliness guidelines for its administrative actions, including for OTSCs.[75] While our review of DEA records appears to indicate that DEA has improved its timeliness in adjudicating OTSCs since the implementation of timeliness guidelines, it also appears that additional improvement is needed. See the text box above.

Improved Data Systems Would Facilitate Better Detection of the Diversion of Pharmaceutical Opioids and New Opioid Analogues

While DEA is responsible for setting the annual quotas for opioid production by manufacturers, and therefore was aware of the substantial growth in the demand for opioids over the past 20 years, we found that DEA did not capture (and still does not capture) sufficient data at the manufacturer, distributor, practitioner, and prescriber levels to enable it to detect the diversion of opioids and identify emerging drug abuse trends.

As described below, DEA uses the Automated Reports and Consolidated Orders System (ARCOS) to monitor manufacturer and distributor inventories, acquisitions, and dispositions of controlled substances. However, the system does not contain current, up-to-date information and does not capture information about all pharmaceutical opioids. Additionally, while DEA's consolidated Suspicious Order Reporting System (SORS), established in 2008, is a potentially useful regulatory tool, we found during our review that it captured suspicious orders from very few registrants. Because SORS does not have data and information on all 1.7 million registrants, we believe that DEA is hampered in its ability to identify and combat the diversion of controlled substances. Further, we found that DEA's ability to use data to respond to emerging drug threats is limited since DEA discontinued the Medical Examiners Database in 2007 and the U.S. Department of Health and Human Services (HHS) discontinued the Drug Abuse Warning Network Live (DAWN

[75] In the 2014 report, OIG made three recommendations to improve DEA's timeliness in adjudicating registrant actions: (1) establishing timeliness standards for adjudicating all OTSCs, (2) establishing policy and procedures for forwarding a case to the Office of the Administrator for final decision when a hearing is waived or terminated, and (3) instituting a formal process for tracking the timeliness of each adjudication. We note that DEA also established several exceptions to its timeliness guidelines, including delays due to other pending cases, record size, case complexity, and the quality of the ALJ's recommendation. DOJ OIG, *DEA's Adjudication of Registrant Actions*. See Appendix 3 for more information.

Live) in 2011.[76] Although DEA is now working with federal and state partners to share data and information, additional improvements, including gaining more access to information from some state-run Prescription Drug Monitoring Programs (PDMP), are necessary. Finally, we found that DEA must continue to strengthen its external partnerships and improve information sharing with state medical and pharmacy boards.

DEA Does Not Capture Sufficient Data to Promptly Detect the Diversion of Opioids and Identify Emerging Drug Trends

We learned that, in order to detect the diversion of controlled substances, DEA investigators use a number of databases, including ARCOS; SORS; and, at one time, DAWN, to detect emerging drug abuse trends. While DEA's diversion detection efforts are critically important in combating the opioid epidemic, we found significant deficiencies that could prevent DEA from promptly detecting potential diversion.

Automated Reports and Consolidated Orders System

According to DEA, ARCOS contains ordering information from about 1,100 manufacturers and distributors for all Schedule I and II controlled substances and certain Schedule III and IV controlled substances.[77] Although DEA officials and staff told us that ARCOS was the primary data tool used to detect the diversion of controlled substances, we found that some manufacturers and distributors report ordering information for Schedule I and II controlled substances to ARCOS on a monthly basis while others report this information on a quarterly basis. This dichotomy of reporting schedules forces DEA to wait a full year before ARCOS contains all of the ordering information needed to fully analyze the data and develop leads and trends. The Associate Section Chief of DEA's Pharmaceutical

[76] In 2019, HHS announced that it would reestablish the DAWN Live database. For more information on DAWN, see HHS Substance Abuse and Mental Health Services Administration, "Drug Abuse Warning Network," www.datafiles.samhsa.gov/study-series/drug-abuse-warning-network-dawn-nid13516 (accessed September 25, 2019).

In response to a working draft of this report, DEA provided the OIG with documentation regarding the expansion of its collaboration with the National Forensics Laboratory Information System (NFLIS), which is as a centralized data collection effort of drug chemistry analysis results from federal, state, and local forensic laboratories (now called NFLIS-Drug). According to DEA, since 1997 NFLIS-Drug has become an operational information system that includes data from 98 percent of the nation's forensic laboratories, reporting approximately 1.5 million drug cases annually. These laboratories analyze substances secured in law enforcement operations across the country, and reporting serves as a valuable resource for monitoring drug trafficking and abuse trends. DEA recently conducted a feasibility study and initiated the expansion of NFLIS to include toxicology and medical examiner and coroner reporting.

[77] More specifically, ARCOS contains ordering information about bulk and/or dosage form controlled substances from manufacturers and distributors that must report inventories, acquisitions, and dispositions of all substances on Schedules I and II, as well as narcotic and gamma-hydroxybutyric acid substances on Schedule III (see 21 C.F.R. § 1308). In addition, manufacturers must report synthesizing activities involving all substances on Schedules I and II, narcotic and gamma-hydroxybutyric acid substances on Schedule III, and selected psychotropic controlled substances on Schedules III and IV (see 21 C.F.R. § 1304.33).

Investigations Section told us that, for example, he would not be able to create the 2017 ARCOS data targeting packages until he received all of the data for 2017, sometime in 2018. Thus, the 2017 ARCOS targeting packages reflected ordering information from 2017 but DEA would not be able to identify issues emerging in 2018 until sometime in 2019. Moreover, DEA cannot create targeting packages for some Schedule III, and all of Schedule IV and V controlled substances, including some opioids, because the registrants for these substances are not required to report ordering information to DEA.

We also found that ARCOS does not contain all of the information necessary to detect the diversion of all pharmaceutical opioids. Some manufacturers and distributors of certain pharmaceutical opioids on Schedules III, IV, and V are not required to report ordering information to DEA. A DEA official told us that DEA did not consider requiring all manufacturers and distributors to report all ordering information when it standardized ARCOS reporting in the late 1970s because DEA thought it was more important to require this of registrants manufacturing and distributing the most dangerous categories of pharmaceuticals, those on Schedules I and II. In fact, as many as 9 opioid compounds found in over 20 pharmaceutical brands were not reported in ARCOS, making it much more difficult to detect the diversion of these prescription drugs.[78]

We are concerned that the nine opioid compounds not reported in ARCOS are just as dangerous to public safety as those on Schedules I and II. For example, a 2016 Florida Medical Examiners Commission report found that tramadol, a Schedule IV controlled substance used to treat moderate to severe pain, was detected in 949 overdose fatalities in Florida since 2015.[79] In addition, ARCOS does not contain ordering information for certain codeine products (such as cough syrup containing codeine, a Schedule V controlled substance) that are particularly susceptible to abuse.[80] DEA officials told us that cough syrups containing codeine are commonly abused throughout the country, particularly along the Southwest border of the United States; however, DEA does not have sufficient data to monitor codeine ordering patterns.

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[78] Pharmaceutical opioids not captured by ARCOS include dextropropoxyphene, difenoxin, tramadol, codeine preparations, difenoxin preparations, dihydrocodeine preparations, diphenoxylate preparations, ethyl morphine preparations, and opium preparations.

[79] Florida Department of Law Enforcement Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners, 2016 Annual Report* (November 2017), www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx (accessed September 25, 2019).

[80] In 2012, DEA reported that more than 1 out of 10 teenagers were abusing cough syrups. Commonly, cough syrups may be abused through drink concoctions such as "lean," a mixture of prescription-strength cough medicine in a soft drink with fruit-flavored candy. Some prescription-strength cough syrups used to make lean also include promethazine, an antihistamine that causes sedative effects and can impair motor function. DEA, *Prescription for Disaster: How Teens Abuse Medicine,* 2nd edition (August 2012), www.getsmartaboutdrugs.gov/sites/getsmartaboutdrugs.com/files/publications/DEA_Prescription-For-Disaster_508ver.pdf (accessed September 25, 2019).

We believe that increasing the reporting requirement in ARCOS to include all controlled substances will allow for a more complete picture of the transactional data of controlled substances. A number of DEA officials we spoke with said that they also believe that the reporting requirement should be expanded, and DEA continues to work with legislators to achieve this.

Further, we learned that ARCOS does not contain ordering information for benzodiazepines, which are Schedule IV controlled substances.[81] DEA officials and staff told us that benzodiazepines, while not opioids, are often used in conjunction with opioids and can produce a particularly lethal drug cocktail often referred to as the "holy trinity."[82] The National Institute on Drug Abuse reported that more than 30 percent of overdoses involving opioids also involve benzodiazepines.[83] The Associate Section Chief of the DEA Pharmaceutical Investigations Section acknowledged ARCOS's shortcomings related to benzodiazepines and other potentially diverted pharmaceuticals. He told us that DEA was "missing the cocktails," i.e., lacking data on the Schedule III, IV, or V controlled substances that are often taken with a Schedule I or II substance. He told us that he wished that ARCOS collected ordering information for all controlled substances. We believe that, due to these deficiencies in ARCOS data, DEA is ill-equipped to effectively monitor ordering patterns for all pharmaceutical opioids, which could enable the diversion of these prescription drugs and compromise public safety.

Suspicious Order Reporting System

Federal regulations require DEA registrants that manufacture and distribute controlled substances to identify and report suspicious orders to DEA and to maintain a system to disclose suspicious order reports to DEA. The *Code of Federal Regulations* defines suspicious orders as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," each of which is a red flag for diversion.[84] In 2008, DEA developed the SORS database, which is maintained and overseen by DEA headquarters to consolidate and house these suspicious order reports.

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[81] According to the National Institute on Drug Abuse, benzodiazepines are pharmaceutical sedatives, including alprazolam, diazepam, and clonazepam, which are commonly prescribed for anxiety or to help with insomnia. National Institutes of Health (NIH) National Institute on Drug Abuse, "Benzodiazepines and Opioids," March 2018, www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids (accessed September 25, 2019).

[82] An AUSA from the USAO for the Eastern District of New York told OIG that the "holy trinity" consists of an opioid used in conjunction with a benzodiazepine and a muscle relaxant such as carisoprodol.

[83] The National Institute on Drug Abuse warns that combining opioids and benzodiazepines can be unsafe because both sedate users, suppress breathing, and impair cognitive functioning and can cause overdose fatalities. NIH National Institute on Drug Abuse, "Benzodiazepines and Opioids."

[84] In addition to reporting a suspicious order to DEA, a registrant that determines that an order is suspicious must not fill it. See also 21 U.S.C. § 823, which codifies 21 C.F.R. § 1301.74.

We found that the SORS database did not include all suspicious reports provided to DEA, thereby significantly impacting its usefulness. This was due largely to the fact that most DEA registrants are not required to report suspicious orders to DEA headquarters. Instead, consistent with federal regulation, nearly all such information is sent to DEA field division offices and DEA has not created a mechanism whereby reports sent to its field divisions are uploaded into the SORS database.[85] As of August 2017, approximately 1,400 DEA registrants were manufacturers and distributors of controlled substances and ARCOS contained ordering information from about 1,100 of these registrants. Yet, we found that the SORS database contained suspicious order reports from only eight registrants. All eight of those registrants were currently, or had been, subject to a Memorandum of Agreement (MOA) with DEA (due to prior violations of DEA regulations) that required them to submit suspicious order reports directly to DEA headquarters.[86]

During interviews, we asked DEA headquarters officials where the remaining suspicious order reports were located for the roughly 1,400 registered manufacturers and distributors of controlled substances; we were informed that DEA requires field divisions to maintain custody of the suspicious order reports. However, when we asked DEA field division staff to locate these reports at multiple sites throughout the country, staff were unaware of the requirement to maintain the reports and could not locate them. One Diversion Program Manager (DPM) described the SORS database as a "joke," noting that DEA field division staff did not receive access to the SORS database until 2017, nearly 10 years after it was created. We believe that the lack of consistent procedures for reporting suspicious orders, and uploading those reports into the SORS database, hampers DEA's ability to detect and target the diversion of controlled substances, including pharmaceutical opioids.

We further found that the current language of 21 C.F.R. § 1301.74(b) does not require manufacturers and distributors reporting suspicious orders to state why they believe an order is suspicious. This results in inconsistencies in reporting because registrants seemingly are applying varying standards and thresholds regarding unusual ordering behavior. This apparent lack of consistent standards creates a risk that suspicious orders may be underreported. The Associate Section Chief of the Pharmaceutical Investigations Section told us that it would help enforcement efforts to have some information on the record regarding why the reporting registrant considered a specific transaction suspicious.

To address these shortcomings, two DEA officials told us that DEA is revising its regulations to mandate that all manufacturers and distributors report suspicious

[85] Pursuant to 21 C.F.R. § 1301.74(b), registrants "shall notify the local DEA field division when suspicious orders are discovered."

[86] The Associate Section Chief of the Pharmaceutical Investigations Section stated that SORS generally captures suspicious orders only from registrants that have an existing MOA that mandates they report suspicious orders to DEA headquarters. Moreover, because MOAs do not exceed 5 years, the number of manufacturers and distributors that are submitting reports to the SORS database fluctuates over time. At the time of our interview with the Associate Section Chief, only one registrant was still required to report suspicious orders to DEA headquarters.

orders to headquarters, not to the field divisions, so that SORS has complete information that can be monitored and analyzed for all registrants. The Associate Section Chief of the Pharmaceutical Investigations Section told us that the revised regulation would help ensure that the data is reported to DEA headquarters consistently from all registrants and that it is appropriately vetted. We agree that the regulations, policies, and procedures should clearly instruct registrants where they should send suspicious order reports and that DEA should ensure that all reports are included in its SORS database. We also believe that DEA should establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report.[87] This is important because most of the major enforcement actions taken against manufacturers and distributors of controlled substances heavily relied on suspicious order reports, or a lack thereof, as evidence that led to administrative actions and settlements that prevented future diversion.

Discontinuation of the Medical Examiners Database in 2007

In 2005, DEA began working with medical examiners to develop a drug abuse warning network called the Medical Examiners Database. We were told that, because medical examiners are often the first to observe the impact of new drugs or analogues, the database allowed them to share their information with DEA, which assisted DEA in more quickly identifying new opioid analogues and assessing emerging overdose trends.[88] Specifically, once a medical examiner determined that a new opioid analogue had caused an overdose death, DEA could receive this "real-time" data and use it to justify formally scheduling the analogue by showing how it had caused harm to the public. In addition, the database improved information sharing among medical examiners, as they could use the data to run toxicology screens and find new drug compounds.

Despite the early success of the Medical Examiners Database, in 2007 then DEA Administrator Michele Leonhart discontinued it after HHS argued that the database contained the same information as HHS's DAWN Live. The current DEA Principal Deputy Administrator, Preston Grubbs, acknowledged that a drug abuse warning network would be beneficial in helping DEA combat the opioid epidemic.

[87] The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, became effective in October 2018. To address the issues discussed above, Sections 3291–3292 on preventing drug diversion codify new standards and definitions with respect to what constitutes a suspicious order. We discuss this change in the law in greater detail at the end of this report.

[88] A controlled substance analogue is a substance that is intended for human consumption, is structurally or pharmacologically similar to or is represented as being similar to a Schedule I or Schedule II substance, and is not an approved medication in the United States. See 21 U.S.C. § 802(32)(A).

DEA Is Working with Federal and State Partners to Share Data, but Additional Improvements Are Necessary

We found that DEA is working with its federal partners, such as HHS and the USAOs, to enhance its data sharing capabilities to facilitate data-driven oversight and improve its regulatory oversight. However, we also found that DEA faces challenges in some field divisions when seeking information from some state-run PDMPs. Such information is vital to DEA's work, given that DEA does not collect information on the prescribing and dispensing behavior of practitioners and pharmacists.

HHS Medicare Data

We found that DEA is working with HHS to facilitate data-driven oversight and improve its regulatory oversight. For instance, the Associate Section Chief of the DEA Pharmaceutical Investigations Section informed us that DEA recently entered into a data-sharing agreement with the HHS Office of Inspector General and that DEA now receives Medicare data, which among other things identifies physicians that are excluded from Medicare billing.[89] The Associate Section Chief told us that if a physician is unable to bill Medicare he or she generally can sustain a practice only through cash payments, which is a red flag for diversion. He also said that if the data shows that a physician was excluded from Medicare due to fraudulent activity DEA can issue an OTSC against the registration.

We note that in October 2018 Congress passed the Substance Use–Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which contains multiple provisions requiring consultation between HHS and DEA.[90] For example, the SUPPORT Act requires HHS, in consultation with DEA, to develop national milestones to measure their success in curbing the opioid epidemic, to report on the impact of federal and state laws and regulations on opioid prescriptions, and to recommend additional steps to limit the over-prescribing of opioids by medical practitioners. The SUPPORT Act also requires DEA to work with HHS to develop special registration procedures for telemedicine. Later in this report, we discuss additional requirements that the SUPPORT Act directed at the Department of Justice and DEA.

In addition, DEA is coordinating with the USAO for the Eastern District of Michigan, which has a program in place to evaluate a series of HHS Medicare data metrics in order to identify physicians throughout the country that may be at high risk for diverting drugs. According to the Associate Section Chief of DEA's Pharmaceutical Investigations Section, the USAO provides DEA headquarters with information packages identifying registrants suspected of diverting controlled substances based on its analysis, which includes HHS Medicare data. DEA headquarters subsequently forwards the information packages to the appropriate

[89] According to DEA, the data sharing agreement with HHS requires the sharing of data/documentation every 6 months. HHS is sharing with DEA mandatory exclusionary documentation on registrants that have controlled substance or Title 18 convictions. DEA is sharing with HHS final disposition arrest data on registrants and non-registrants, as its exclusion authority is extensive.

[90] The SUPPORT Act, Pub. L. No. 115-271, Title VII, Subtitle C, Public Health Provisions, §§ 7021–7024.

field divisions. Later in this report, we discuss how these information packages generate leads and result in diversion investigations.

Prescription Drug Monitoring Programs

As described in the Introduction, PDMPs are state-run databases that include prescription information on doctors, dentists, pharmacies, and patients and that electronically monitor and house records regarding dispensed pharmaceutical drugs that contain controlled substances. The goal of the PDMP is to assist medical professionals and state regulators in the identification and prevention of prescription drug abuse. However, numerous DEA Diversion Investigators and Special Agents told us that they experience challenges in accessing PDMP information, which hinders their ability to investigate registrants that are suspected of diverting prescription drugs.

DEA staff told us that state-run PDMPs contain important and useful prescription information that helps investigators identify anomalies in physicians' prescribing practices. States, however, have significantly varying requirements regarding how DEA can obtain access to this information. Some states permit DEA to access their PDMP data provided there is an open law-enforcement investigation, while other states require DEA to have an administrative subpoena or a search warrant.[91] One state, Vermont, prohibits law enforcement from obtaining PDMP information under any circumstance, which we were told creates significant challenges for DEA Diversion Investigators in a state with one of the highest opioid overdose rates in the country.[92]

[91] Under federal law, law enforcement must demonstrate probable cause that a crime has occurred in order to meet the threshold for a search warrant (see Rule 41 of the *Federal Rules of Criminal Procedure*). For an administrative subpoena, law enforcement must demonstrate only reasonable suspicion that a crime has occurred, a much lower threshold (see 21 U.S.C. § 876).

We note that in FY 2003 the Department's Bureau of Justice Assistance developed the Harold Rogers Prescription Drug Monitoring Grant Program to assist in the implementation and enhancement of state-run PDMPs, including by developing data-driven strategies to address prescription drug abuse, misuse, and diversion within local communities. The grant announcement envisions that states will collaborate and share data and information regarding unsolicited prescriber and patient prescription histories with law enforcement investigators, regulatory agencies, and licensing boards to target prescription drug abuse and diversion. The announcement also states that the Bureau of Justice Assistance administers the program in coordination with several federal agencies, including DEA. While we did not evaluate this program as part of this review, it is puzzling to OIG that DEA Diversion Investigators and Special Agents, who should be able to receive PDMP data and information from this DOJ-funded program, still face challenges to their ability to access the PDMP in some states, especially given that the Department has funded this program since FY 2003.

See DOJ Office of Justice Programs Bureau of Justice Assistance, "Harold Rogers Prescription Drug Monitoring Program, FY 2016 Competitive Grant Announcement," April 16, 2016, OMB No. 1121-0329, www.bja.gov/funding/PDMP16.pdf (accessed September 25, 2019).

[92] According to the National Institute on Drug Abuse, Vermont had 101 opioid-related overdose deaths in 2016, a rate of 18.4 deaths per 100,000 persons, which exceeds the national rate of 13.3 opioid-related overdose deaths per 100,000 persons. NIH National Institute on Drug Abuse, "Vermont Opioid Summary," March 2019, www.drugabuse.gov/opioid-summaries-by-state/vermont-opioid-summary (accessed September 25, 2019).

In response to these issues, the Department and DEA have taken steps to enhance DEA's access to PDMP data. In 2017, a Ninth Circuit decision held that an administrative subpoena was sufficient to obtain PDMP information and that access did not violate privacy interests.[93] In turn, several states within the Ninth Circuit, including Utah and California, began allowing DEA to use an administrative subpoena to gain PDMP access, rather than requiring a search warrant. An Attorney Advisor with the Department's Office of Legislative Affairs stated that DEA has engaged with and will continue to work with congressional offices on solutions that will furnish law enforcement with access to state PDMP data while protecting individual patient privacy.

The Associate Section Chief of the Pharmaceutical Investigations Section also told us that in December 2017 DEA started negotiating a data sharing agreement with states that were seeking ARCOS data from DEA, which in turn may afford DEA improved access to these states' PDMP data. Finally, the Bureau of Justice Assistance funded a PDMP data hub, called RxCheck, which offers states the opportunity to securely and efficiently share PDMP data with other states. As of June 2018, RxCheck could facilitate prescription data sharing with only 5 states (Florida, Oklahoma, Alabama, Maine, and Kentucky) and 10 more states were in the process of joining the program.[94]

For DEA to better perform its regulatory responsibilities and to cooperate with states to prevent any future epidemics, we believe that the Department and DEA should continue to work with states to reach agreements that will enable DEA to have timely access to PDMP prescription data as needed to effectively perform its regulatory and law enforcement responsibilities while also ensuring adequate protections for the important healthcare privacy interests of patients.

State Pharmacy and Medical Boards

Another area in which DEA needs to improve its information sharing is with state medical and pharmacy boards. For example, we learned that DEA is not always notified in a timely manner of actions that state pharmacy and medical boards take against physicians, pharmacists, and pharmacies. We were told that, as a result, physicians were able to continue to prescribe opioids and other controlled substances even after their medical licenses were revoked because DEA was not aware of the license revocations.

In addition, a former Tactical Diversion Squad (TDS) Group Supervisor told us that DEA needs to foster better working relationships with its external stakeholders, including state boards. According to this former DEA official, the

[93] See *Oregon Prescription Drug Monitoring Program* v. *U.S. Drug Enforcement Admin.*, 860 F.3d 1228 (9th Cir. 2017).

[94] According to the Bureau of Justice Assistance, an additional 9 states (West Virginia, Tennessee, Rhode Island, Arizona, North Dakota, Nebraska, Wisconsin, Georgia, and Vermont) have expressed interest in joining RxCheck. Their participation, added to that of the states mentioned above, would expand the initiative to as many as 24 states.

state Board of Pharmacy he was working for when we interviewed him had 50 inspectors, all of which were licensed pharmacists. He stated that given their subject matter expertise these inspectors would be a great resource for DEA to use during pharmacy inspections, which DEA recently added to the Diversion Control work plan. However, at the time of our interview such coordination had not occurred.[95]

We believe that DEA must continue to work to foster relationships with state medical and pharmacy boards in order to keep these state entities informed about DEA regulations and registrant reporting requirements, as well as any administrative enforcement actions that DEA takes against registrants. This would also help to ensure that DEA is kept apprised of any administrative actions that state boards take against registrants.

The Department and DEA Have Taken Steps to Address the Opioid Epidemic as a National Crisis

We found that the Department and DEA have taken steps to address the opioid epidemic as a national crisis. For example, in November 2015 DEA announced the piloting of its 360 Strategy to combat the opioid epidemic.[96] The strategy involves coordinated law enforcement efforts with federal, state, and local partners; diversion control enforcement actions; and community outreach through local partnerships to provide support in outreach, education, and prevention. In 2018 DEA conducted a 45-day enforcement surge, which resulted in 273 enforcement actions; however, we found that some of these actions were scheduled investigations routinely conducted as part of DEA's annual Diversion Control work plan. Additionally, DEA is making an effort to increase both Diversion Investigator and Special Agent staffing levels in the field divisions located in areas hardest hit by the opioid epidemic. Further, the Department's Opioid Fraud and Abuse Detection Unit began providing targeting packages to the USAOs, which have generated leads and resulted in ongoing DEA investigations. Finally, as discussed

[95] At the time of our review, DEA had several opioid-related initiatives with state and federal partners, including the National Healthcare Fraud Takedown, National Takeback Initiative, Memoranda of Understanding with state Attorneys General for Data Sharing, and National Opioid Strike Forces with the Department and other federal partners. In addition, the DEA Special Operations Division and Diversion Control Division are in discussions with the U.S. Food and Drug Administration to collaborate on a joint "Warning Letter" campaign to officially notify purported internet pharmacy website owners to discontinue their alleged illegal activity.

In addition to this review, OIG is conducting an audit of DEA's prescription drug take back activities.

[96] At the time of our review, DEA had deployed its 360 Strategy in 12 pilot cities for 1 year in each city. DEA, "DEA 360 Strategy: Overview," www.dea.gov/prevention/360-strategy/360-strategy.shtml (accessed September 25, 2018).

above, the SUPPORT Act, enacted in October 2018 to combat the opioid epidemic, includes several provisions that may help DEA increase its enforcement efforts.

DEA's 360 Strategy Has Improved Its Community Outreach Efforts, but DEA Needs to Assess the Effect on Diversion Control Enforcement Actions

In November 2015, DEA began implementing its 360 Strategy in cities across the country to respond to the heroin and prescription opioid pill crisis. According to DEA, its 360 Strategy combats opioid abuse using a three-pronged approach: (1) coordinating law enforcement actions against drug cartels and heroin traffickers in specific communities, (2) leveraging diversion control enforcement actions against DEA registrants operating outside the law, and (3) pursuing community outreach through local partnerships that empower communities to take back affected neighborhoods and prevent problems from recurring.[97] Based on interviews with DEA officials, including those responsible for implementing the 360 Strategy in West Virginia and Ohio, two states hit hard by the opioid epidemic, we found that the program has improved DEA's community outreach efforts to raise awareness of the dangers of opioids and increased intelligence sharing with law enforcement in the community.[98]

However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine how the program's diversion-related activities impact the field divisions' diversion control enforcement capabilities.[99] According to the DEA headquarters official responsible for the 360 Strategy, in 2017 DEA hired an independent, third-party consultant to

[97] Diversion control enforcement actions consist of ISOs, OTSCs, MOAs, and Letters of Admonition. Depending on the severity of a registrant's conduct, DEA may suspend, revoke, or deny a DEA registration by issuing an ISO or OTSC; enter into a written contract, known as an MOA, with the registrant, which could place greater restrictions or conditions on the registrant; or issue a Letter of Admonition, which officially warns the registrant to resolve minor infractions. Based on our review of DEA's administrative enforcement data, we found that the 360 Strategy did not have a material effect on DEA's administrative enforcement actions in 360-designated locations. For instance, while DEA launched the 360 Strategy in Manchester, New Hampshire; Charleston, West Virginia; and Dayton, Ohio, in FY 2017, DEA issued only one OTSC and no ISOs against registrants operating in these three states during FY 2017.

OIG is conducting an audit of DEA's community-based efforts to combat the opioid crisis. See DOJ OIG, "Ongoing Work," www.oig.justice.gov/ongoing/dea.htm (accessed September 25, 2019).

[98] The Assistant Special Agent in Charge in the West Virginia field office at the time of our review told us that the 360 Strategy facilitated greater coordination with law enforcement in the community. However, he also said that intelligence sharing and deconfliction among DEA, local law enforcement, and the USAO was an ongoing issue that needed to be resolved. Consequently, he believes that law enforcement is "missing a lot of the boat on exploiting [the] case beyond the borders."

[99] According to DEA, the goals of the 360 Strategy include: (1) stopping the deadly cycle of heroin and opioid pill abuse by eliminating drug trafficking organizations and gangs fueling violence on the streets and cycles of addiction in our communities, (2) partnering with the medical community and others to raise awareness of the dangers of prescription opioid misuse and the link to heroin, and (3) strengthening community organizations best positioned to provide long-term help and support for building drug-free communities.

assess DEA's implementation efforts for two 360 Strategy pilot cities with a goal to evaluate additional pilot cities to measure the effectiveness of the program. We reviewed two independent consultant reports completed during our review and found that they do not address or evaluate DEA's diversion control enforcement efforts. Also, according to three DPMs that oversee DEA's Diversion Control Program in 360 Strategy pilot cities, the program has not enhanced their field divisions' diversion control enforcement efforts.[100]

In addition, a 2018 U.S. Government Accountability Office (GAO) report found that the 360 Strategy did not include goals or performance measures for two parts of the strategy: "enforcement operations and diversion control initiatives."[101] GAO recommended that the DEA Administrator establish goals and outcome-oriented performance measures for enforcement and diversion control activities and establish outcome-oriented performance measures for community engagement activities within the 360 Strategy.[102] According to GAO, DEA was considering applying its Threat Enforcement Planning Process to the 360 Strategy to develop outcome-oriented metrics, which includes an impact report that assesses the strategy's effect of DEA's enforcement and diversion control activities.[103] However, GAO noted that these efforts are yet to be fully implemented and it is too soon to assess whether these efforts fully address GAO's recommendation.

While DEA's community outreach efforts are notable, DEA cannot demonstrate that the implementation of its 360 Strategy has changed its diversion control enforcement efforts in response to the opioid crisis. We believe that DEA must assess whether the program is meeting all of its objectives and that DEA must establish measureable performance metrics that show how the 360 Strategy enhances DEA's ability to bring diversion control enforcement actions against registrants that may be diverting pharmaceutical opioids.

DEA Has Taken Steps to Pursue Administrative Cases

Unlike DEA's response to the OxyContin crisis, which targeted all registrants, including opioid distributors and manufacturers, in February 2018 DEA surged its enforcement and administrative resources to identify and investigate prescribers and pharmacies that dispensed disproportionately large amounts of controlled substances. During the surge, DEA suspended its scheduled regulatory

[100] Additionally, in June 2018 the Section Chief for the DEA Planning and Resource Section stated that, while DEA provides additional funding to 360 Strategy pilot city offices, these funds are largely allocated for public outreach efforts as opposed to bolstering offices' diversion control enforcement efforts against registrants that may be diverting controlled substances.

[101] See GAO, *Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts,* GAO-18-205 (March 2018), www.gao.gov/assets/700/690972.pdf (accessed September 25, 2019).

[102] GAO, *Illicit Opioids,* 65.

[103] According to DEA's FY 2019 budget request, the Threat Enforcement Planning Process uses data analysis to maximize the allocation of resources and personnel against DEA-wide national level threats.

investigations so that the DEA Diversion Control staff could focus on specific leads and targets.[104] The goal of the surge was to remediate or remove prescriber and pharmacy registrants whose actions "perpetuate the controlled prescription drug crisis in America, particularly opioid drugs."[105]

According to DEA, the 45-day enforcement surge resulted in 273 enforcement actions. However, we found that these actions included scheduled regulatory investigations that DEA would have conducted as part of its annual Diversion Control work plan and that these scheduled investigations did not specifically target the diversion of pharmaceutical opioids. The inclusion of these scheduled investigations increased DEA's reported enforcement data by almost 15 percent. Additionally, we found that only 15 (5 percent) of the 273 enforcement actions that DEA issued were OTSCs (10) or ISOs (5).[106]

While DEA's Diversion Control Staffing Had Declined Nationally During the Opioid Epidemic, DEA Is Now Making Efforts to Increase Staff in Locations Hardest Hit by the Opioid Epidemic

Although the DEA registrant population has increased on average by about 40,000 registrants each year, we found that DEA's enforcement staffing has not grown at the same rate during the opioid epidemic. Over the last decade, the registrant population grew from about 1.29 million registrants in FY 2007 to over 1.7 million registrants by the end of FY 2017. As a result, the ratio of registrants to Diversion Investigators increased by over 30 percent in the past decade, from about 2,500 to 1 in FY 2007 (a total of 509 Diversion Investigators) to about 3,300 to 1 by FY 2017 (a total of 511 Diversion Investigators).

Based on our review of DEA data, we found that Diversion Investigator staffing increased by about 20 percent during our scope (from 422 in FY 2010 to 511 in FY 2017) but has slightly decreased since FY 2015. Meanwhile, Special Agent staffing decreased by about 10 percent from FY 2010 to FY 2017 (from 5,006 in FY 2010 to 4,506 in FY 2017). See Figure 5 below.

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[104] DOJ, Press Release No. 18-290, "DEA Surge in Drug Diversion Investigations Leads to 28 Arrests and 147 Revoked Registrations," April 2, 2018, www.justice.gov/opa/pr/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked-registrations (accessed September 25, 2019).

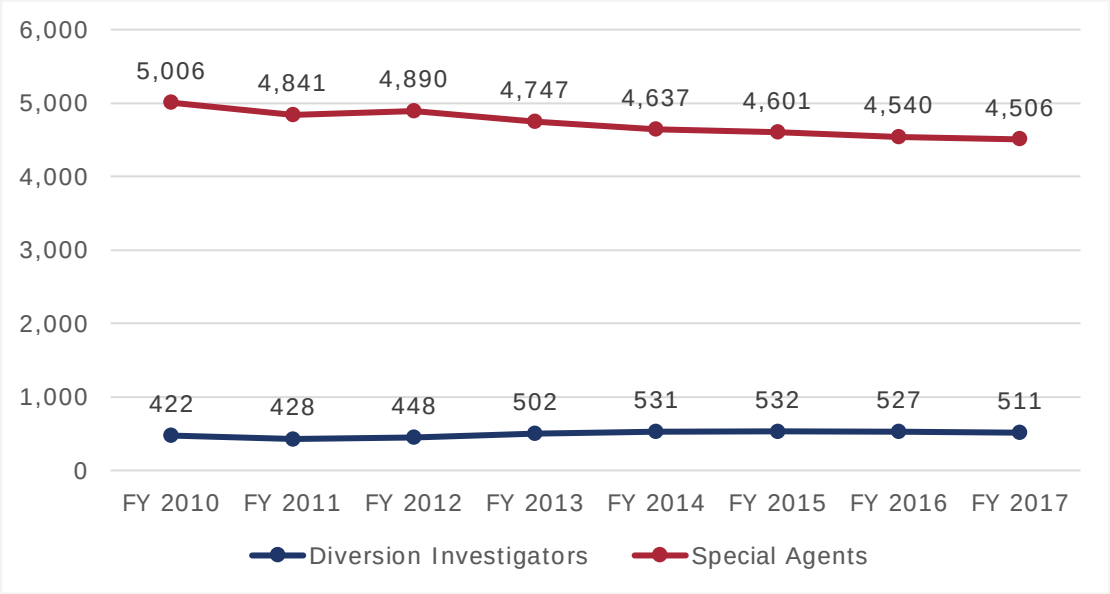
In response to a working draft of this report, DEA provided to the OIG a January 2018 email from the Deputy Assistant Administrator, Office of Diversion Control Operations, to Special Agents in Charge, Assistant Special Agents in Charge, and DPMs in all DEA field divisions regarding the suspension of regulatory scheduled investigations during the 45-day enforcement surge. The 45–60 day suspension of scheduled investigations was imposed so that DEA diversion staff could focus on specific leads and targets.

[105] DOJ, Press Release No. 18-290.

[106] Former acting DEA Administrator Patterson told us that he did not know why the results from scheduled investigations were included in the reported numbers because these activities were already part of the field division work plans that were approved at the beginning of FY 2017. He further stated that although these scheduled investigations did not specifically target pharmaceutical opioid diversion, they coincidentally produced results during the 45-day surge.

Figure 5

Diversion Investigator and Special Agent Staffing, FYs 2010–2017



Source: OIG analysis of DEA data

Throughout the course of our review, many DEA officials and staff told us that DEA did not have adequate staffing to combat the opioid epidemic in their local areas. For instance, by 2016 West Virginia had the highest rate of opioid-related overdose deaths (43.4 deaths per 100,000 people) in the United States, with the majority of deaths attributed to synthetic opioids, such as oxycodone, hydrocodone, and heroin.[107] However, we found that until 2016 DEA had established only one TDS to cover the entire state of West Virginia.[108] As of August 2017, DEA's two West Virginia offices had 13 Special Agents and 6 Diversion Investigators that were responsible for regulating over 10,000 registrants throughout the entire state.[109] In addition, a DPM told us that DEA did not have adequate staffing in Florida, a state that has historically faced challenges with combating the diversion of opioids.[110]

[107] See NIH National Institute on Drug Abuse, "West Virginia Opioid Summary," March 2019, www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/west-virginia-opioid-summary (accessed September 25, 2019).

[108] In 2016, DEA established a second TDS located in Clarksburg, West Virginia.

[109] In January 2018, DEA established the Louisville Field Division to manage its diversion control efforts in West Virginia, Tennessee, and Kentucky. According to DEA, the new division was established to unify DEA's drug trafficking investigations throughout the Appalachian mountain region, which has been "impacted by an increasing amount of activity related to heroin, fentanyl, and prescription opioid trafficking." In addition, the new division provides better alignment between DEA and corresponding USAO districts.

[110] As we discussed above, there was a high volume of diversion in Florida during the early part of our scope. In fact, it was in Florida that DEA launched both Operation Pill Nation (2011) and Operation Pill Nation II (2012), which together led to 118 arrests, the surrender of more than 80 DEA registrations, the seizure of more than $19 million in assets, and the closure of at least 40 pain clinics.

The official told us that DEA had only about 20 Diversion Investigators that were responsible for regulating over 88,000 Florida registrants in the "pill mill capital of the world."

During our interview with then acting DEA Administrator Patterson, he acknowledged DEA's staffing shortfalls but noted that DEA could bring on only so many new staff at one time due to physical limitations at its training academy.[111] He told us that DEA anticipates hosting 2 new Diversion Investigator classes and 7 new Special Agent classes through FY 2019, which together will add 100 new Diversion Investigators and 350 new Special Agents to DEA's roster of employees. In addition, the Section Chief for the Planning and Resources Section told us that DEA plans to more than double its Diversion Investigator staffing, to about 1,100 positions nationwide over the next decade. The Section Chief added that if Congress provided DEA with direct hiring authority for diversion staff, as it has for Special Agent positions, DEA could hire candidates more quickly.[112] However, as of June 2019, DEA had not made a formal request to obtain direct hiring authority to staff Diversion Investigator positions.

To Supplement DEA's Diversion Control Efforts, the Department Created the Opioid Fraud and Abuse Detection Unit

The Department is responsible for prosecuting opioid-related cases primarily through the U.S. Attorney's Offices (USAO), with Assistant U.S. Attorneys (AUSA) exercising their discretion in determining whether and how to move forward with a case once a DEA Diversion Investigator or Special Agent presents evidence of violations.[113] However, we found that DEA's ability to bring federal criminal charges against registrants is challenging, due in part to a lack of resources within some USAOs to prosecute pharmaceutical opioid cases.

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[111] In contrast to most DEA positions, Diversion Control staff, including TDS Special Agents, are funded by the Diversion Control Fee Account, which collects registration fees from manufacturers, distributors, dispensers, importers, and exporters of controlled substances and certain regulated chemicals. Although Congress must still approve proposed increases to DEA's staffing levels, DEA's Diversion Control funding is not limited to the traditional resource constraints of most government agencies. For instance, DEA reported that the Diversion Control Fee Account had generated over $416 million through registrant fees and maintained a balance of $175 million in FY 2017. Meanwhile, DEA reported that the National Diversion Control Program cost $420 million in FY 2017.

[112] According to our review on gender equity throughout the Department's law enforcement components, the Bureau of Alcohol, Tobacco, Firearms and Explosives; Federal Bureau of Investigation; and DEA may all use excepted service hiring authority for certain positions and issue position announcements in specific locations or cities based on need. The use of excepted service hiring authority increases an agency's applicant pool and offers targeted recruitment opportunities. See DOJ OIG, *Review of Gender Equity in the Department's Law Enforcement Components,* E&I Report 18-03 (June 2018), www.oig.justice.gov/reports/2018/e1803.pdf (accessed September 25, 2019). Although DEA may use excepted service hiring authority for Special Agents, Intelligence Research Specialists, and Task Force positions, DEA does not have this authority for diversion-specific positions.

[113] DEA Diversion Control Manual, Section 5263.2, 37.

To address this issue, in the fall of 2017 the Department established the Opioid Fraud and Abuse Detection Unit, a pilot program that uses data to focus on opioid-related healthcare fraud cases.[114] The Opioid Fraud and Abuse Detection Unit provides targeting packages, which identify registrants suspected of diverting controlled substances, to AUSAs selected from USAO districts across the country to assist in identifying and prosecuting individuals that are contributing to the opioid epidemic.[115] During our interviews with AUSAs assigned to the Opioid Fraud and Abuse Detection Unit, we learned that these packages have supplemented some of DEA's diversion efforts, generated leads, and resulted in ongoing investigations of overprescribing medical professionals and pharmacy thefts. We also learned that requests for targeting packages have expanded beyond the initial 12 USAO districts. We believe that these packages have the potential to benefit more USAOs across the country.[116]

Legislation Intended to Combat the Opioid Epidemic May Help DEA Increase Its Enforcement Efforts

In October 2018, the SUPPORT Act was signed into law to combat the opioid crisis. The SUPPORT Act includes provisions to reduce the number of illegal opioids and excess prescription opioids that are available, to share data to address over-prescribing, and to authorize new support for community efforts to reduce the

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[114] DOJ, Press Release No. 17-861, "Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit," August 2, 2017, www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit (accessed September 25, 2019).

[115] At the time the program started, the Department initially selected 12 USAOs including the (1) Middle District of Florida, (2) Eastern District of Michigan, (3) Northern District of Alabama, (4) Eastern District of Tennessee, (5) District of Nevada, (6) Eastern District of Kentucky, (7) District of Maryland, (8) Western District of Pennsylvania, (9) Southern District of Ohio, (10) Eastern District of California, (11) Middle District of North Carolina, and (12) Southern District of West Virginia. In response to a working draft of this report, the Executive Office for U.S. Attorneys told us that the Eastern District of California was no longer participating in the program.

[116] In response to a working draft of this report, the Executive Office for U.S. Attorneys told us that dissemination is not limited to particular USAOs and that any USAO that requests a package can get one. Additionally, the DOJ Criminal Division and DEA noted additional steps taken by the Department, DEA, and state and federal partners to address the opioid epidemic as a national crisis. These steps include the creation of the Appalachian Regional Prescription Opioid Strike Force in October 2018, as well as some actions taken outside the scope of this review, such as two National Health Care Fraud Takedowns in July 2017 and June 2018.

DOJ, Press Release, "Appalachian Regional Prescription Opioid Strike Force Takedown," April 17, 2019, www.justice.gov/usao-sdwv/pr/appalachian-regional-prescription-opioid-strike-force-takedown-0 (accessed September 25, 2019).

DOJ, Press Release No. 18-1388, "Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions," October 25, 2018, www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid (accessed September 25, 2019).

DOJ, Press Release No. 18-866, "National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses," June 28, 2018, www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over (accessed September 25, 2019).

availability of illicit opioids. According to DEA officials, the SUPPORT Act also increases some of DEA's authorities to combat the opioid epidemic. Based on our review of the SUPPORT Act, as well as DEA documents summarizing its provisions, we found that it amends several provisions of the Controlled Substances Act of 1970 (CSA), codifies DEA regulations, and creates new reporting requirements for DEA to Congress and the states, which could address some of the concerns we identified throughout this report.[117]

For example, the SUPPORT Act codifies the new quota regulation regarding the factors that the DEA Administrator can consider when determining the Aggregate Production Quota (APQ).[118] We also found that the SUPPORT Act requires DEA to establish a centralized database for collecting reports of suspicious orders from all registrants. In addition, it requires DEA to make a standardized report regarding suspicious orders available to state regulatory and licensing agencies, Attorneys General, and law enforcement agencies. The SUPPORT Act explicitly defines the term "suspicious order" to ensure consistency and aid registrants in making reports.[119]

Further, the SUPPORT Act includes several provisions regarding the Automated Reports and Consolidated Orders System (ARCOS), which we found cannot detect the diversion of all pharmaceuticals, including some Schedule III and all Schedule IV and V opioids and other controlled substances. Below, we list the SUPPORT Act requirements that are relevant to our review:

- On a quarterly basis, DEA will provide drug manufacturers and distributors with access to anonymized information from ARCOS to assist them in identifying, reporting, and stopping suspicious orders of opioids. All registered manufacturers and distributors must review the information provided by DEA.[120] The SUPPORT Act also amends the CSA to establish civil and criminal penalties for registered manufacturers and distributors for failing

[117] The CSA requires that each person or firm that proposes to handle controlled substances or List I chemicals obtain a DEA registration unless exempted.

[118] Proposed Rules, 21 C.F.R. Part 1303, Docket No. DEA–480, RIN 1117–AB48, Controlled Substance Quotas, 83 Fed. Reg. 76,17329 (Apr. 19, 2018), www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0419.htm (accessed June 28, 2018). On July 16, 2018, the proposed rule became final, and it became effective on August 15, 2018. See Final Rule, 21 C.F.R. Part 1303, Docket No. DEA–480, RIN 1117–AB48, Controlled Substance Quotas, 83 Fed. Reg. 136,32784 (Jul. 16, 2018).

As discussed in the Introduction, the APQ is the maximum amount of each basic class of Schedule I and II controlled substances that the DEA Administrator deems necessary for manufacture in a calendar year, by all pharmaceutical manufacturers combined, for the estimated medical, scientific, research, and industrial needs of the United States or for lawful export.

See also the SUPPORT Act, Pub. L. No. 115-271, Title VII, Subtitle C, Quota Reform, §§ 3281–3282.

[119] The SUPPORT Act, Title III, Subtitle B, Chapter 9, §§ 3291–3292.

[120] Title III, Subtitle B, §§ 3272 and 3273 of the SUPPORT Act establish that if the Department initiates proceedings against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or for violations of the CSA, the Department may take into account that anonymized ARCOS data was made available to the registrant.

to review quarterly ARCOS data, failing to report suspicious orders of opioids, or failing to maintain effective controls.[121]

- The Department will prepare a standardized report and make it available to state regulatory and licensing agencies, Attorneys General, and law enforcement agencies in those states that the Department determines have the highest rate of opioid abuse. The report will contain descriptive and analytic information on the actual distribution patterns gathered from ARCOS, which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants in such states for Schedule II controlled substances.[122] The report must be provided to the entities every 6 months.
- The Department will report to Congress on how the Department is using ARCOS to identify and stop suspicious activity, including whether the Department is looking at aggregate orders from individual pharmacies to multiple distributors that in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributor.[123]

Finally, the SUPPORT Act includes provisions requiring DEA to promulgate certain regulations. For example, while the legislation does not mandate electronic prescribing, it does instruct DEA to update its regulations that require multifactor authentication to access e-prescribing tools so that they include biometric components, such as fingerprint, thumbprint, and voice, as an approved means of authentication.[124]

Given that the SUPPORT Act was passed in October 2018, we are unable to measure or even predict its effect on the opioid crisis or DEA's opioid enforcement efforts. However, we believe that the legislation contains several provisions that could help DEA address some of the issues that we identified in this report.

[121] The SUPPORT Act, Title III, Subtitle B, § 3273(c), Using Data to Prevent Opioid Diversion, amends 21 U.S.C. § 842 and § 402 of the CSA.

[122] The SUPPORT Act, Title III, Subtitle B, § 3273(b), amends 21 U.S.C. § 873 and § 503 of the CSA.

[123] The SUPPORT Act, Title III, Subtitle B, § 3274.

[124] The SUPPORT Act, Title II, § 2003, Every Prescription Conveyed Securely.

CONCLUSION AND RECOMMENDATIONS

Conclusion

As the United States is confronted with one of the worst drug epidemics in its history, with opioid-related overdoses accounting for more than 47,600 deaths in 2017, an estimated 35 percent of which involved a prescription opioid, we found that DEA was slow to respond to this crisis in a number of ways. First, unlike past drug crises, in combating the current opioid epidemic DEA failed to develop a comprehensive national strategy that could have focused and directed its regulatory and enforcement efforts. For example, as the rate of opioid use and abuse in the United States continued to increase from 1999 to 2016, the amount of opioid manufacturing authorized by DEA also increased dramatically during that same time. We found that DEA did not reduce the Aggregate Production Quota for most controlled substances until 2016, the year during which opioid production fell by 25 percent.

Second, in November 2015 DEA initiated its 360 Strategy, which was publicly touted as a program with a focus on law enforcement efforts, diversion control, and community outreach. However, we found that the goals of DEA's 360 Strategy do not specifically address diversion control enforcement efforts and that DEA cannot determine how the program's diversion-related activities impact its field divisions' diversion control enforcement capabilities. While DEA's community outreach efforts are notable, we believe that DEA must assess how the 360 Strategy impacts DEA's ability to bring diversion control enforcement actions against registrants that may be diverting pharmaceutical opioids.

Third, DEA does not capture sufficient data to detect the diversion of opioids or identify emerging drug abuse trends. Specifically, we found that DEA's system that monitors registrants' ordering patterns and behavior cannot detect the diversion of all pharmaceuticals, including some Schedule III, IV, and V opioids and other controlled substances. As a result, possible prescription abuse and diversion of these controlled substances are likely undetected. We also found that DEA's database to track registrant suspicious order reports is not used by the majority of its registrants, with only 8 registrants reporting suspicious orders to DEA in this manner. While we were told that the remaining registrants continue to report suspicious orders to local field division offices, DEA field division staff at multiple sites could not locate suspicious order reports when we asked them.

Fourth, we believe that DEA needs to bolster its recent efforts to work more closely with other federal and state partners to improve data sharing. For example, we found that DEA Special Agents and Diversion Investigators continue to face challenges accessing pharmacy and patient-level information from state-run Prescription Drug Monitoring Programs. The level of access to this data varies across states, and we believe that timely and consistent access to this information could improve DEA's ability to investigate registrants that may be diverting pharmaceutical opioids.

Fifth, DEA did not fully utilize its regulatory authorities and enforcement resources to detect diversion. We found that DEA regulations fail to assess the suitability of potential new registrants, which may prevent DEA from identifying registrants whose applications merit heightened scrutiny. These regulations hinder DEA's ability to prevent the diversion of all controlled substances, including pharmaceutical opioids. We also found that DEA did not maximize its resources to investigate diversion. Specifically, in the majority of cases DEA did not use its strongest enforcement tool, the Immediate Suspension Order (ISO), to combat diversion. Despite reports that pointed to the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, or the "Marino Bill," as impeding DEA's ability to issue ISOs, we found that there was a reduction in the number of ISOs issued by DEA 3 years before the passage of this legislation. Also, we believe that the decline in ISOs was related to two key factors: the end of DEA's successful efforts to take down "pill mills" and the poor working relationship between DEA's Office of Chief Counsel and Diversion Control staff.

Further, we found that the Department and DEA have taken some recent steps to address the opioid epidemic, but that significant work remains. While DEA's enforcement staffing declined nationally during the opioid epidemic, at the time of our review DEA was making efforts to increase Diversion Investigator and Special Agent staffing levels. The Department's Opioid Fraud and Abuse Detection Unit also began providing targeting packages to 12 U.S. Attorney's Offices across the country, which, we were told, produced leads and supplemented ongoing opioid-related investigations. Finally, the enactment of the Substance Use–Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act in October 2018 directed the Department and DEA to take several important steps to enhance enforcement efforts to combat the opioid epidemic. We believe that these legislative changes are a positive step; however, more must be done, including the possibility of additional regulatory changes, for the Department and DEA to effectively target registrants that engage in the diversion of opioids.

Recommendations

To more effectively target registrants that engage in the diversion of opioids, we recommend that DEA:

1. Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combating the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.

2. Require criminal background investigations of all new registrant applicants.

3. Implement electronic prescribing for all controlled substance prescriptions.

4. Require that all suspicious orders reports be sent to DEA headquarters.

5. Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants'

history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.

6. Revise field division work plan requirements to allow the flexibility to target registrants for investigation.

7. Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues and respond to these threats in a timely manner.

To improve its efforts to combat the diversion of pharmaceutical opioids, as well as prosecute registrants that divert pharmaceutical opioids, we recommend that the Department:

8. Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs.

9. Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.

APPENDIX 1

PURPOSE, SCOPE, AND METHODOLOGY

Standards

OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation* (January 2012).

Data Analysis

We reviewed data related to all opioid anti-diversion activities from FY 2010 through FY 2017. Data included all investigations opened and closed by the Office of Diversion Control (OD); civil and criminal case filings against distributors, manufacturers, pharmacies, and doctors; Immediate Suspension Orders (ISO), Orders to Show Cause (OTSC), Letters of Admonition, and Memoranda of Agreement against registrants; voluntary surrenders; and other administrative enforcement actions brought against opioid distributors and manufacturers. We also reviewed all fines that DEA levied against opioid manufacturers, distributors, doctors, and pharmacies, including the amount, date, and recipient of each fine.

Site Visits

We visited or conducted virtual site visits with eight DEA field divisions: (1) Washington, D.C.; (2) New England; (3) San Diego; (4) Los Angeles; (5) Miami; (6) New York; (7) Detroit; and (8) Denver. We selected these sites based on our analysis of opioid overdose data from the Centers for Disease Control and Prevention. In total, we spoke to DEA staff in 17 states and territories that were impacted by the opioid epidemic: (1) California; (2) Connecticut; (3) Denver; (4) Florida; (5) Maine; (6) Maryland; (7) Massachusetts; (8) Michigan; (9) New Hampshire; (10) New York; (11) Ohio; (12) Rhode Island; (13) Utah; (14) Vermont; (15) Virginia; (16) Washington, D.C.; and (17) West Virginia.

Interviews

The team conducted 252 interviews during the course of our review, including interviews with DEA Diversion Investigators, Special Agents, Task Force Officers, Intelligence Analysts, Diversion Program Managers, Assistant Special Agents in Charge, and Special Agents in Charge. We also conducted interviews with senior officials at DEA headquarters, including the former acting DEA Administrator; the Principal Deputy Assistant Administrator; the Chief of Operations; current and former Assistant Administrators for the OD; the Deputy Chief Counsel; Section Chiefs or Associate Section Chiefs for the United Nations Reporting and Quota Section, Pharmaceutical Investigations Section, Planning and Resources Section, Community Outreach and Prevention Support Section, Liaison and Policy Section, Regulatory Drafting and Policy Support Section, Regulatory Section, Diversion & Regulatory Litigation Section, and Registration and Program

Support Section; and Chief Counsel attorneys.[125] In addition, we interviewed officials and staff across 31 U.S. Attorney's Offices, including Assistant U.S. Attorneys, Narcotics Chiefs, Criminal Chiefs, Civil Chiefs, and the U.S. Attorney for the District of New Hampshire. Finally, we interviewed senior officials in the Department's Office of the Deputy Attorney General and the Section Chief for the Criminal Division's Narcotic and Dangerous Drug Section.

Policy and Document Review

We reviewed diversion control regulations, policies, procedures, and charging documents, including every ISO and OTSC that DEA issued from FY 2010 through FY 2017. In addition, we reviewed case file documents for eight cases, as well as corresponding case emails.

Timeliness Analysis

To evaluate DEA's timeliness in adjudicating administrative enforcement actions against registrants, we reviewed 642 ISOs and OTSCs, as well as subsequent DEA Administrator decisions provided to us by DEA. During our review of these documents, we captured many fields of information, including but not limited to the name of the registrant, the type of registrant, the type of administrative enforcement action, the date that the administrative enforcement action was issued, the registrant's proposed hearing date, the submission date of the Administrative Law Judge's (ALJ) recommendation to the Office of the Administrator (when available), and the date of the DEA Administrator's final decision (when applicable). To assess DEA's timeliness, we calculated the length of time it took for the Office of the Administrator to issue a final decision after receiving the ALJ's recommendation and the total length of time to complete the administrative process (from issuance to final decision).

Although our methodology allowed for both qualitative and quantitative analysis, it also produced several limitations. First, we could measure the total length of time for only about 40 percent (265 out of 642 cases) of all cases we reviewed because many cases did not culminate with a final decision by the DEA Administrator during our scope. For instance, we excluded from our analysis registrants that surrendered their DEA registration after receiving the charging document or whose case remained pending at the end of our scope. Second, we were able to determine the submission date of the ALJ's recommendation for only about 35 percent (97 out of 265 cases) of all cases that resulted with a final decision by the DEA Administrator during our scope because that information was not regularly provided in the DEA Administrator's decision. In addition, even when we could determine the ALJ's submission date for certain cases, the majority of these cases arose during the first half of our scope, which made it more difficult for us to conduct a reliable annual assessment of DEA's timeliness efforts. Lastly, due to differences in methodology, we were unable to compare our timeliness analysis

[125] The OIG made several attempts to obtain technical comments and feedback from former acting DEA Administrator Robert Patterson on our working draft report. Despite our efforts, we were unable to obtain Patterson's comments and input.

to OIG's 2014 report, which also assessed DEA's timeliness in adjudicating enforcement actions against registrants.

APPENDIX 2

DEA DATABASES USED TO COMBAT THE DIVERSION OF CONTROLLED SUBSTANCES

In the Introduction for this report, we briefly describe a number of databases that DEA uses to combat the diversion of controlled substances and to target registrants that may be diverting pharmaceutical opioids. We discuss these systems in greater detail below.

Automated Reports and Consolidated Orders System

The Automated Reports and Consolidated Orders System (ARCOS) is DEA's automated system to monitor Schedule II and some Schedule III controlled substances. ARCOS reporting requirements are specific to manufacturers and distributors under 21 C.F.R. § 1304. Manufacturers and distributors must use ARCOS to report inventories, acquisitions, and dispositions to DEA. ARCOS allows DEA to maintain current and historical records of inventories and transactions of selected controlled substances from drug manufacturers to distributors and other entities within the closed system of distribution, including pharmacies at the dispensing level.

Drug Theft or Loss Reporting Requirements

DEA requires all registrants that handle controlled substances to report theft or loss of a controlled substance to their local DEA field division in writing within 1 business day of discovering the loss, according to the *Code of Federal Regulations.*[126] Registrants have the option to report a lost or stolen controlled substance to DEA by paper submission; however, to minimize errors, DEA encourages registrants to report theft or loss of a controlled substance through the online Theft or Loss System.[127]

Registrant Information Consolidated System

The Registrant Information Consolidated System (RICS), also known as CSA II, is a database that consolidates several of DEA's internal systems, including the Quotas, ARCOS, and CSA databases, providing real-time access to registrant actions and information. DEA uses RICS to manage all registrant records. In addition, RICS allows DEA field divisions to know when registrants are being investigated at the national level to avoid duplicate efforts.

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[126] 21 C.F.R. § 1301.76(b).

[127] Registrants may also report the theft or loss of controlled substances regulated by DEA using DEA Form 106. DEA's Theft or Loss System, the online equivalent to the DEA Form 106, allows registrants to report information with fewer errors using the National Drug Code to populate fields that would identify the manufacturer, product, dosage format, and size of the package.

Suspicious Order Reporting System

Under the *Code of Federal Regulations,* manufacturers and distributors are required to develop and maintain a system to identify suspicious order requests and to report the information to DEA.[128] Manufacturers and distributors are further required, in accordance with the *U.S. Code,* to maintain effective controls to keep substances from being diverted outside of legitimate medical, scientific, or industrial needs.[129] Most suspicious orders should be reported directly to the local DEA field division unless the registrant has been directed through a Memorandum of Agreement to submit such activity to the Suspicious Order Reporting System (SORS) overseen by DEA headquarters. Suspicious orders are defined as unusual quantities or deviations from normal ordering practices. DEA registrant numbers are linked to suspicious order reports and, once such reports are populated in SORS, the system can show suspicious order activity throughout the nation.

[128] 21 C.F.R. § 1301.74(b).

[129] 21 U.S.C. § 823.

APPENDIX 3

PRIOR WORK ON DEA DIVERSION EFFORTS

Related to opioid enforcement, DOJ OIG and the U.S. Government Accountability Office (GAO) have conducted eight previous reviews, which examined whether DEA has taken steps to improve its ability to control the diversion of opioids:

1. DOJ OIG, *Review of the Drug Enforcement Administration's Control of the Diversion of Controlled Pharmaceuticals* (September 2002).[130] The review concluded that DEA was slow to commit sufficient resources to address the widespread problem of controlled pharmaceutical diversion and abuse. We also found that DEA continued to devote a significantly lower percentage of its criminal investigation resources to controlled pharmaceutical diversion than to criminal investigations of illicit drugs, such as cocaine, heroin, and methamphetamines.
2. DOJ OIG, *Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals* (July 2006).[131] The review concluded that although DEA had taken steps to combat the diversion of controlled pharmaceuticals, some areas needed further improvement. We also found that, since our September 2002 review, diversion using the internet had become a growing threat and that DEA had not provided Diversion Investigators with the tools necessary to conduct successful investigations.
3. DOJ OIG, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014).[132] The review concluded that DEA's process to adjudicate registrants' actions and issue final decisions was compliant with applicable laws and regulations. However, the review found that DEA did not have timeliness standards for the adjudication process and that DEA was slow to reach final adjudication.
4. GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (December 2003).[133] This review concluded that although federal and state agencies and Purdue Pharma, OxyContin's manufacturer, had taken actions to address the abuse and diversion of OxyContin, there was room for improvement. GAO recommended that the U.S. Food and Drug Administration and Purdue Pharma implement a stronger safety warning on OxyContin's label and that both use a coordinated risk

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[130] See DOJ OIG, *Review of the Drug Enforcement Administration's Control of the Diversion of Controlled Pharmaceuticals*, E&I Report I-2002-010 (September 2002), www.oig.justice.gov/reports/DEA/e0210/index.htm (accessed September 25, 2019).

[131] See DOJ OIG, *Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals,* E&I Report I-2006-004 (July 2006), www.oig.justice.gov/reports/DEA/e0604/index.htm (accessed September 25, 2019).

[132] See DOJ OIG, *The Drug Enforcement Administration's Adjudication of Registrant Actions,* E&I Report I-2014-003 (May 2014), www.oig.justice.gov/reports/2014/e1403.pdf (accessed April 16, 2019).

[133] See GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem,* GAO-04-110 (December 2003), www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/pdf/GAOREPORTS-GAO-04-110.pdf (accessed September 25, 2019).

management plan to help detect and prevent OxyContin abuse. DEA's OxyContin National Action Plan and its successes were highlighted as an effective means of addressing the abuse and diversion of this drug.

5. GAO, *Controlled Substances: DEA Should Take Additional Actions to Reduce Risks in Monitoring the Continued Eligibility of Its Registrants* (May 2016).[134] The review concluded that DEA had established controls for determining registrant eligibility to handle and prescribe controlled substances. However, limitations in DEA's controls did not help to ensure that individual registrants were and remained eligible and did not present issues that may increase the risk of illicit diversion.

6. GAO, *Department of Justice, Drug Enforcement Administration: Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder* (February 2018).[135] The review found that a new provision in statute allowed DEA to expand the categories of practitioners that may dispense Schedule III, IV, and V narcotic drug treatments for opioid abuse.

7. GAO, *Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries* (May 2018).[136] The review concluded that while the Centers for Medicare and Medicaid Services provided guidance to opioid prescription plan sponsors, recent criteria did not provide sufficient information on the large population of beneficiaries at risk of harm from opioid use.

8. GAO, *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access* (June 2015).[137] The review found that some DEA registrants, particularly chain pharmacy and distributor corporate offices, had better communication with DEA about their regulatory roles and responsibilities. The review concluded that some chain and individual pharmacies, distributors, and practitioners wanted improved communication and guidance from DEA regarding regulatory requirements.

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[134] See GAO, *Controlled Substances: DEA Should Take Additional Actions to Reduce Risks in Monitoring the Continued Eligibility of Its Registrants,* GAO-16-310 (May 2016), www.gao.gov/products/GAO-16-310 (accessed September 25, 2019).

[135] See GAO, *Department of Justice, Drug Enforcement Administration: Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder,* B-329747 (February 2018), www.gao.gov/products/D18622 (accessed September 25, 2019).

[136] See GAO, *Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries,* GAO-18-585T (May 2018), www.gao.gov/products/GAO-18-585T (accessed September 25, 2019).

[137] See GAO, *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (June 2015), www.gao.gov/products/GAO-15-471 (accessed September 25, 2019).

APPENDIX 4

DEA'S RESPONSE TO THE DRAFT REPORT

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

SEP 25 2019

MEMORANDUM

TO: Nina Pelletier
Assistant Inspector General for
Evaluation and Inspections
Office of the Inspector General

FROM: Mary B. Schaefer
Chief Compliance Officer
Office of Compliance

SUBJECT: DEA Response to the OIG Final Report, "Review of Regulatory and Enforcement Efforts to Control the Diversion of Opioids"

The Drug Enforcement Administration (DEA) has reviewed the Department of Justice (DOJ) Office of the Inspector General's (OIG) Evaluation and Inspections Division report entitled, "Review of Regulatory and Enforcement Efforts to Control the Diversion of Opioids." DEA appreciates the OIG's assessment of DEA's ongoing efforts to combat the diversion of prescription opioids. While the report rightly identifies areas for improvement, we believe that it is important to both highlight the positive progress that DEA has made in the last several years, and to provide context to some of the key observations made in the report.

The DEA uses a wide array of tools – administrative, civil, and criminal – to fight the diversion of controlled substances. While only a minute fraction of the more than 1.8 million DEA registrants are involved in unlawful activity of this nature, DEA works to identify and root out the bad actors – whether they are manufacturers, distributors, pharmacies, or prescribers. In the past eight years, DEA has removed approximately 900 registrations annually, preventing further diversion of controlled substances. Working with United States Attorney's Offices across the country, an increasing number of individuals and corporations are facing civil and criminal charges for actions that have fueled the opioid crisis. The information below provides recent highlights of DEA's efforts in this area:

- In July 2019, two former corporate officers of Miami-Luken, a pharmaceutical distributor, and two pharmacists were indicted on charges that they conspired to illegally distribute and dispense controlled substances. The indictment alleges that the distributor and its officials filled suspicious orders, including distributing over a four year period more than 3.7 million hydrocodone pills to a pharmacy in a town of 400 people.

- In April 2019, in a first-of-its-kind prosecution, two executives of Rochester Drug Cooperative (RDC), one of the ten largest pharmaceutical distributors in the United States, and the distributor itself were charged with drug trafficking and conspiring to defraud the DEA. As alleged, RDC knowingly and intentionally violated the federal narcotics laws by distributing dangerous, highly addictive opioids to pharmacy customers that it knew were being sold and used illicitly.

- DEA has pursued civil actions against some of the nation's largest drug distributors. In FY 2017, DEA secured more than $194 million in civil penalties, which is more than the total of the prior seven years combined. As of August 2019, DEA has secured over $51 million in civil penalties.

- In the last three years, DEA has reduced by over 45% the aggregate production quota for the seven most frequently diverted controlled substance opioids. DEA's 2020 quota proposal would bring this to 53% if implemented. There has been a precipitous decline in the number of opioid prescriptions since the beginning of this Administration as well: comparing January 2017 to August 2019, the number of prescriptions for those seven opioids has decreased by nearly 30%.

- DEA also works to educate its registrant community in an effort to stop potential diversion before it occurs. DEA has educated over 13,000 pharmacists and other pharmacy personnel in all 50 states, D.C., and Puerto Rico, and is now hosting similar events for practitioners (*e.g.*, doctors, dentists, veterinarians) to educate them on pre-emptive steps that can be taken to prevent diversion. Since May 2018, DEA has held 25 conferences in 13 locations, reaching over 5,800 healthcare professionals.

- DEA also utilizes its administrative authority to remove registrations from individuals or entities who act contrary to the public interest. Last fiscal year, DEA issued 20 Immediate Suspension Orders (ISOs), 71 Orders to Show Cause (OTSC), and obtained 774 surrenders for cause. The statistics for this fiscal year are likely to meet or exceed those from FY 2018.

These recent accomplishments build on several years of impactful partnership between DEA's Diversion Control Division and the Office of Chief Counsel. Below, we provide additional information in response to the report's findings that DEA did not use its available resources, including its administrative enforcement tools and data systems, to detect and regulate diversion effectively.

In finding that DEA's use of the ISO enforcement tool decreased from FY 2011 through FY 2015, and again in FY 2017, as compared to prior years, the report does not fully take into account the factors that contributed to that decline. As acknowledged in the report, DEA previously identified several factors relevant to the decrease.[1] These included: the substantial decline in opioid prescriptions since 2012 and the concomitant shift in diversion from prescription opioids to heroin/fentanyl, the past reluctance of U.S. Attorney's Offices to allow DEA to proceed administratively if parallel criminal investigations/matters were pending, DEA's strategic shift in 2011-2012 to target "upstream" registrants, the increase of registration surrenders, and the lack of

[1] *See* Report at 23-24, nn. 67 & 69.

adequate training of DEA investigation personnel on administrative remedies (including ISOs).

The report focuses only on two of these factors—"the end of DEA's successful efforts to take down 'pill mills' and the poor working relationship between DEA's Office of Chief Counsel and Diversion Control staff."[2] While DEA concurs that the end of Operations Pill Nation I & II in Florida, and other large-scale DEA enforcement operations was unquestionably significant in terms of the decline in ISOs after 2012, DEA believes that the report overstates the purported impact of the working relationship between the Office of Chief Counsel and the Office of Diversion Control on the decline in ISOs.

For example, although DEA produced files on 992 cases, the report discusses only two of them. Thus, in over 99% of the cases, the OIG appears to have found no evidence that discord between the Office of Chief Counsel and Diversion Control Division played a role in the decision to pursue an ISO. Moreover, even in the two cases discussed in the report, a lack of cooperation was not the reason that an ISO was not issued in either case. In one case, investigative personnel did not seek administrative action against the target for over a year after the alleged misconduct occurred. The ISO was not issued because at that point it was too late to show "imminent danger" based on the evidence presented. In the second case, as the report correctly recognizes, the Office of Chief Counsel was denied access to a medical expert. In that case, the testimony was essential to support administrative action and the ISO could not be issued without it.[3]

The report accurately observes that federal courts reviewing DEA ISOs had previously faulted DEA for presenting insufficient evidence.[4] In response to this criticism, DEA redoubled its efforts to ensure that the cases it presented were supported by adequate evidence. Though two subsequent cases were discussed where further information was requested by the Office of Chief Counsel, these requests were consistent with what the courts and pertinent case law require.

In failing to give adequate consideration to the other factors contributing to the decline in ISOs, the report disproportionately suggests that the decline in ISOs was due primarily to shortcomings at DEA. In fact, as the additional information DEA provided demonstrates, positive factors such as the decline in opioid prescriptions since 2012 and the increase in registration surrenders also contributed to the decline in ISOs.

As the case disposition data that DEA provided to OIG shows, although DEA issued fewer ISOs after 2012, between FY 2010 and FY 2019, the DEA charged 68.5% of the cases presented. This number rises to 82.6% when one accounts for cases that were favorably terminated prior to the issuance of a charging document (e.g., registrants surrendered their registration prior to charging).[5]

Additionally, the Office of Chief Counsel has declined only 7.6% of the cases opened during the review period, and when years FY 2018 and FY 2019 are included, that number drops to 6.5%.[6]

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2 Report at 47.
3 Report at 25, n.71.
4 *See* Report at 23-24 (discussing *Cardinal* ISO federal court litigation).
5 *Id.* FY2019 data was provided through June 26, 2019.
6 *Id.* Since DEA charged or terminated 82.6% of the cases and declined to charge 7.6% of them, the remaining cases were either settled prior to the issuance of a charging document (4%) (*e.g.*, McKesson), held at the request of DEA investigators

Importantly, the percentage of cases declined has decreased by over 60% during the review period. For the first half of the review period (FY 2010-FY 2013), the declination rate was 9.7%. For the second half (FY 2014-FY 2017), the declination rate was less than half that, or 4.0%. When the second portion of the review period is extended to include FY2018 and FY2019 to date, the percentage of cases declined drops to 2.8%. No case has been declined since FY 2016.

DEA believes that this additional context is important to clarify the reasons for the declines in ISOs during the review period. DEA appreciates OIG's recognition that although discord once existed between the Office of Chief Counsel and the Diversion Control Division, it does not exist today, and has not for years. DEA further believes that collaboration between the Office of Chief Counsel and the Diversion Control Division has produced demonstrable results. Changes in DEA senior leadership in 2015-2016 substantially improved the relationship between the two offices, which currently enjoy a productive, collaborative working relationship.

Other factors also enhanced the working relationship between the offices. For more than three years now, the Office of Chief Counsel's Diversion & Regulatory Litigation Section (CCD) and the Diversion Control Division's Pharmaceutical Investigations Section (DOP) have partnered to provide additional training and assistance to DEA investigators, jointly conducting hundreds of site visits and trainings to increase field investigative personnel's awareness of, and familiarity with, DEA administrative proceedings and the associated evidentiary requirements.

This training regarding case investigation and preparation, in combination with the revised case intake process, has significantly improved the quality of case files presented for administrative action, which in turn speeds case initiation. As the quality of case files improves, cases can be charged more quickly. In FY 2016, for example, the median amount of time between receiving a case file and issuing a charging document was 24 days. By FY 2018, that time had declined to 15 days. As of the end of FY 2018, there were no uncharged cases pending in the Office of Chief Counsel, which has the capacity and capability to review additional cases.

These improvements in training and process have yielded results. In FY 2018, for example, DEA charged 91 cases administratively (71 OTSCs, 20 ISOs). This upward trend continues, as DEA has charged 100 cases (72 OTSCs, 28 ISOs) in FY2019 to date.[7] And as noted previously, no cases have been declined since FY 2016.

DEA anticipates that this positive cycle will continue. Many investigative personnel who previously worked in DOP and alongside CCD have now been promoted to senior leadership positions in various field divisions. Due to their expertise in administrative revocation proceedings, these personnel are working to remedy many of the training issues noted in the past. These personnel are also poised to collaborate with CCD and facilitate even greater use of the DEA administrative process.

With respect to parallel proceedings, the Office of Chief Counsel and Diversion Control Division have jointly worked with field investigative personnel to ensure that DEA pursues ISOs when feasible in parallel with criminal investigations/matters. As such collaborations continue to be

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or US Attorney's Offices (5.5%), or are cases in which investigative personnel are working to obtain additional materials (0.3%).

7 FY2019 aggregate case data through September 12, 2019.

successful, DEA is optimistic that the historical reticence to allow DEA to proceed administratively in parallel with criminal proceedings will dissipate.

** ** **

OIG made a total of nine recommendations in this report, in which seven recommendations are directed to DEA. DEA provides the following responses to its recommendations:

Recommendation 1. Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combatting the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.

DEA RESPONSE

DEA concurs with this recommendation. Although the Office of National Drug Control Policy is the entity within the federal government responsible for developing a national opioid enforcement strategy, DEA will undertake an internal review to develop a DEA-wide national prescription opioid enforcement strategy that incorporates the work of all DEA field divisions, to include metrics of performance to measure the strategy's progress.

Recommendation 2. Require criminal background investigations of all new registrant applicants.

DEA RESPONSE

DEA concurs with the recommendation. DEA agrees that it would be useful to require background investigations of all new registrant applicants. Currently, Diversion Control Division's Registrant Program Specialists (RPS) are authorized to request background checks on new registrant applications through a third party company. The Diversion Control Division is in the final approval process of issuing a guidance memorandum to its RPS staff that background checks on new registrant applications are mandatory, effective immediately. The scheduled issue date of the memorandum is anticipated to be October 1, 2019. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

Recommendation 3. Implement electronic prescribing for all controlled substance prescriptions.

DEA RESPONSE

DEA concurs with the recommendation. The electronic prescribing of controlled substance prescriptions is already authorized for those practitioners who wish to do so. On March 31, 2010, DEA published in the Federal Register an interim final rule entitled, "Electronic Prescriptions for Controlled Substances." The effective date of this rule was June 1, 2010. Additionally, the SUPPORT Act (PL 115-271) signed into law on October 24, 2018, requires DEA, within one year of the law's enactment, to update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances. DEA is working to publish a final rule on the electronic prescribing of controlled

substances. This rule is on the Unified Agenda as a DOJ and Administration priority.

Recommendation 4: Require that all suspicious orders reports be sent to DEA headquarters.

DEA RESPONSE

DEA concurs with the recommendation. DEA agrees that all suspicious order reports should be sent to DEA headquarters. Registrants are currently required to report suspicious orders to the Field Division Office. 21 C.F.R. 1301.74(b). The SUPPORT Act requires that DEA establish a centralized database for collecting reports of suspicious orders within one year of the law's enactment. DEA is currently working to finalize the database for release by the statutorily mandated deadline of October 23, 2019. Additionally, DEA is drafting regulations pertaining to suspicious orders. This regulation is on the Unified Agenda as a DOJ and Administration priority.

Recommendation 5. Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants' history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.

DEA RESPONSE

DEA concurs with the recommendation. DEA's current registration application forms already include a set of liability questions that require the applicant to disclose, on pain of a material falsification charge, information including registration revocations/surrenders and state licensure actions.

When an applicant answers any liability question in the affirmative, DEA initiates a pre-registration inquiry to further explore the applicant's response.

It is important to note that DEA lacks the authority to amend or alter the Controlled Substances Act (CSA) via guidance documents. Rather, guidance must come from agency case law applying the CSA, which specifies the legal considerations that guide the public interest analysis in DEA administrative proceedings, including reapplications. This case law provides extensive guidance on the application of the CSA's remedial framework and the relevant factors that DEA must consider under the CSA. For many years, DEA's Diversion Control Division has published all registration adjudication opinions on its website, which is available to the public and DEA investigative personnel.

Since 2015, DEA's Office of Chief Counsel has also produced its Deskbook, a reference handbook for diversion investigative personnel that is intended to address common questions and issues that frequently arise in registration investigations/adjudications. The Office of Chief Counsel has revised and disseminated the Deskbook three times. The Deskbook explains the pertinent criteria and legal analysis that DEA must apply under the CSA.

In response to this recommendation, DEA will examine the current pre-registration inquiry process and guidance to see if improvements can be made to better ensure that DEA Diversion Control Division personnel responsible for adjudicating registrant reapplications are fully informed of the standards for review when conducting a pre-registration inquiry. DEA will then report to the OIG on any changes that are deemed necessary.

Recommendation 6. Revise field division work plan requirements to allow the flexibility to target registrants for investigation.

DEA RESPONSE

DEA concurs with the recommendation. DEA agrees that it is important to allow flexibility to target registrants for investigation. The 2019 work plan was modified to allow the flexibility for the field to investigate threats in their area of responsibility. Per the FY 2019 work plan parameters, scheduled investigations were required to be completed on a registrant within five years of the last completed scheduled investigation. As such, the FY 2019 work plan covered FY 2019 – FY 2023. It allowed each division to have the flexibility to create their scheduled investigation work plan, based on identified concerns by division management and to choose a time frame for a scheduled investigation between one to five years. It is important to note that these dates are fluid and can be modified at any time to meet the threat assessment in each field division's area of responsibility. The Diversion Control Division has the authority to issue new work plans as needed to outline any changes that are determined to be necessary to address the ever changing landscape of diversion of controlled substances. The Diversion Control Division's strategy is to focus efforts on investigations that will aggressively combat the opioid epidemic and emerging drug threats. The Diversion Control Division is in the final approval stages of issuing a memorandum with new scheduled investigation guidance for FY2020. The anticipated issue date of this memorandum is October 1, 2019, and it will be distributed to all of the Diversion Control Division field offices. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

Recommendation 7. Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues, and respond to these threats in a timely manner.

DEA RESPONSE

DEA agrees that identifying and responding to emerging drug abuse trends is important to protect public health and safety, and the Diversion Control Division has a number of existing programs and initiatives to identify new and emerging drug threats.

The National Forensic Laboratory Information System (NFLIS) began in September 1997 as a single data collection effort of drug chemistry analysis results from local, state, and federal forensic laboratories (now called NFLIS-Drug). These laboratories analyze substances recovered/seized in law enforcement operations across the country. NFLIS-Drug is a valuable resource for monitoring illegal drug abuse and trafficking, including the diversion of legally manufactured pharmaceutical drugs into illegal markets. NFLIS-Drug data is used to support drug regulatory and scheduling efforts and to inform drug policy and drug enforcement initiatives nationally and in local communities.

NFLIS-Drug includes data from forensic laboratories that conduct analyses of approximately 98% of the Nation's approximate 1.5 million annual drug cases. As of February 2019, NFLIS-Drug includes 50 State systems and 104 local or municipal laboratories/laboratory systems, representing a total of 283 individual laboratories. A recent example of how NFLIS data is used is the NFLIS-Drug Special Release Maps, which highlight fentanyl and selected fentanyl-related substances reported to NFLIS-Drug in 2016 and 2017, and can be found on the NFLIS website.

Recently, DEA expanded the NFLIS program to include (1) public and private toxicology laboratory (NFLIS-Tox) data regarding postmortem and antemortem toxicological testing, and (2) medical examiner and coroner office (NFLIS-MEC) data regarding deaths in which drugs were identified. These two continuous data collection programs complement NFLIS-Drug and further support the DEA's drug regulatory and scheduling efforts. NFLIS recently reported findings from the 2017 Toxicology Laboratory Survey and 2017 Medical Examiner and Coroner Survey in support of starting the NFLIS-Tox and NFLIS-MEC programs.

In addition to the existing NFLIS system and our NFLIS enhancements, DEA recently initiated a contract with the University of California at San Francisco (UCSF) whereby biological samples generated from overdose victims of synthetic drugs can be further analyzed. This program's goal is to connect symptom causation and newly emerging synthetic drugs (i.e. synthetic cannabinoids, synthetic cathinones, fentanyl-related substances, other hallucinogens etc.). In addition to identifying new and emerging drugs of abuse, this program will assist investigators in building "death resulting from" cases against those who traffic controlled substances.

DEA will work with OIG to provide proof of these efforts and move towards closure of this recommendation.

Thank you for the opportunity to respond and address the OIG's concerns. If you have any questions regarding this response, please contact DEA's Audit Liaison Team at 202-307-8200.

APPENDIX 5

OIG ANALYSIS OF DEA'S RESPONSE

OIG provided a draft of this report to DEA. DEA's formal response to the recommendations in the report is included in Appendix 4. DEA concurred with all of OIG's recommendations. Below, we discuss OIG's analysis of DEA's formal response and actions necessary to close the recommendations.

Separately, DEA's response questions the report's finding that a historically poor working relationship between the Office of Chief Counsel (CCD) and the Office of Diversion Control (OD) impacted DEA's use of Immediate Suspension Orders (ISO). In support of its position, DEA states that it "produced files on 992 cases [and] the report discusses only two of them. Thus, in over 99% of the cases, the OIG appears to have found no evidence that discord between [CCD] and [OD] played a role in the decision to pursue an ISO." We do not agree with DEA's position. First, DEA's response fails to mention what we were told by former long-time DEA agent and acting DEA Administrator Patterson, namely that the relationship between field division Diversion Control staff, OD, and CCD had historically been "toxic." Second, as clearly stated in the report, the two cases discussed were cited as examples of the discord we found, consistent with former acting Administrator Patterson's statement. The fact that the report does not discuss the remaining 990 cases does not support a conclusion that "OIG appears to have found no evidence of discord" in those cases. We continue to believe that our finding is supported by the evidence we obtained during our review; however, as stated in the report, and as DEA describes in its response, we believe that DEA has taken recent steps to address the issue and improve this relationship.

Recommendation 1: Develop a national prescription opioid enforcement strategy that encompasses the work of all DEA field divisions tasked with combating the diversion of controlled substances, and establish performance metrics to measure the strategy's progress.

Status: Resolved.

DEA Response: DEA concurred with the recommendation and stated that it will undertake an internal review to develop a national prescription opioid enforcement strategy that incorporates the work of all DEA field divisions and includes performance metrics to measure the strategy's progress.

OIG Analysis: DEA's actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a status update regarding DEA's efforts to develop a national prescription opioid enforcement strategy that includes performance metrics to measure the strategy's progress and incorporates the work of all DEA field divisions.

Recommendation 2: Require criminal background investigations of all new registrant applicants.

Status: Resolved.

DEA Response: DEA concurred with the recommendation and agrees that it would be useful to require background investigations on all new registrant applicants. Currently, the Diversion Control Division's Registrant Program Specialists (RPS) are authorized to request background investigations on new registrant applications through a third party company. On October 1, 2019, the Diversion Control Division plans to issue a guidance memorandum to its RPS staff requiring mandatory background investigations on new registrant applications. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

OIG Analysis: DEA's actions are responsive to our recommendation, provided that the anticipated guidance memorandum requires RPS staff to request "criminal" background investigations on all new registrant applications. By January 3, 2020, please provide a copy of the guidance memorandum to RPS staff and confirm that the type of background investigations now required are in fact "criminal" background investigations.

Recommendation 3: Implement electronic prescribing for all controlled substance prescriptions.

Status: Resolved.

DEA Response: DEA concurred with the recommendation. The electronic prescribing of controlled substance prescriptions is already authorized for those practitioners who wish to do so. On March 31, 2010, DEA published in the *Federal Register* an interim final rule entitled, "Electronic Prescriptions for Controlled Substances," which became effective on June 1, 2010. Additionally, the Substance Use–Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (PL 115-271), signed into law on October 24, 2018, requires DEA, within 1 year of the law's enactment, to update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances. DEA is working to publish a final rule on the electronic prescribing of controlled substances. This rule is on the Unified Agenda as a Department and Administration priority.

OIG Analysis: DEA's anticipated actions are partially responsive to our recommendation. While there are several rules DEA proposed on the Unified Agenda of the Office of Management and Budget at various stages in the rulemaking process, the OIG was unable to locate publicly available documentation that pertains to the publication of a final rule on mandatory electronic prescribing for all controlled substances. By January 3, 2020, please provide a status update and clarification regarding the publication of this anticipated final rule.

Recommendation 4: Require that all suspicious orders reports be sent to DEA headquarters.

Status: Resolved.

DEA Response: DEA concurred with the recommendation and agrees that all suspicious order reports should be sent to DEA headquarters. In accordance

with 21 C.F.R. 1301.74(b), registrants are currently required to report suspicious orders to DEA Field Divisions. However, since the enactment of the SUPPORT Act, DEA is required to implement the use of a centralized database for the collection of suspicious order reports. The statute requires that the database is functional by October 23, 2019. Additionally, DEA is drafting regulations pertaining to suspicious orders. This regulation is on the Unified Agenda as a Department and Administration priority.

OIG Analysis: DEA's actions are responsive to our recommendation. The OIG has confirmed that the proposed rule, which defines the term "suspicious order" and provides clarity to the registrant community on its reporting obligations, directly addresses the corrective action recommended in our report. In addition, the implementation of a centralized database for the collection of suspicious order reports also directly addresses the corrective action recommended. By January 3, 2020, please provide documentation confirming that suspicious order reports are being collected and housed in the new database and provide a status update regarding the proposed rulemaking regarding suspicious orders.

Recommendation 5: Take steps to ensure that DEA diversion control personnel responsible for adjudicating registrant reapplications are fully informed of the applicants' history resulting in a prior registration being revoked by DEA, surrendering a prior registration for cause, losing a state medical license, or other conduct which may threaten the public health and safety by improving information provided to such personnel about the standards to apply in making decisions on such applications.

Status: Resolved.

DEA Response: DEA concurred with the recommendation. DEA's current registration application forms already include a set of liability questions that require the applicant to disclose, on pain of a material falsification charge, information including registration revocations/surrenders and state licensure actions. When an applicant answers any liability question in the affirmative, DEA initiates a pre-registration inquiry to further explore the applicant's response.

It is important to note that DEA lacks the authority to amend or alter the Controlled Substances Act (CSA) via guidance documents. Rather, guidance must come from agency case law applying the CSA, which specifies the legal considerations that guide the public interest analysis in DEA administrative proceedings, including reapplications. This case law provides extensive guidance on the application of the CSA's remedial framework and the relevant factors that DEA must consider under the CSA. For many years, DEA's Diversion Control Division has published all registration adjudication opinions on its website, which is available to the public and DEA investigative personnel.

Since 2015, DEA's CCD also produced, revised, and disseminated its Deskbook, a reference handbook for diversion investigative personnel that is intended to address common questions and issues that frequently arise in

registration investigations/adjudications. The Deskbook explains the pertinent criteria and legal analysis that DEA must apply under the CSA.

In response to this recommendation, DEA will examine the current pre-registration inquiry process and guidance to see whether improvements can be made to better ensure that DEA Diversion Control Division personnel responsible for adjudicating registrant reapplications are fully informed of the standards for review when conducting a pre-registration inquiry. DEA will then report to OIG on any changes that are deemed necessary.

OIG Analysis: DEA's actions are responsive to our recommendation. By January 3, 2020, please provide a status update regarding DEA's examination of the current pre-registraton inquiry process and guidance documents associated with that process and describe any improvements DEA plans to make.

Recommendation 6: Revise field division work plan requirements to allow the flexibility to target registrants for investigation.

Status: Resolved.

DEA Response: DEA concurred with the recommendation and reported that its FY 2019 Diversion Control work plan was modified to allow flexibility for each field division to investigate threats in its area of responsibility. More specifically, DEA stated that the FY 2019 work plan allowed each division to create its scheduled investigation work plan based on concerns identified by division management and to choose a time frame for a scheduled investigation between 1 to 5 years. DEA also acknowledged that these dates are fluid and can be modified at any time to meet the threat assessment in each field division's area of responsibility. Further, DEA stated that the Diversion Control Division has the authority to issue new work plans as needed to outline any changes that are determined to be necessary to address the ever changing landscape of the diversion of controlled substances. Moreover, DEA reported that the Diversion Control Division is in the final approval stages of issuing a memorandum with new scheduled investigation guidance for FY 2020. DEA anticipates that this guidance will be issued to all Diversion Control Division field offices on October 1, 2019. DEA will provide OIG with a copy of this memorandum as soon as it is issued.

OIG Analysis: DEA's anticipated actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a copy of the FY 2020 scheduled investigation guidance memorandum that extends the flexibilities outlined in the FY 2019 work plan.

Recommendation 7: Revive a drug abuse warning network to identify emerging drug abuse trends and new drug analogues and respond to these threats in a timely manner.

Status: Resolved.

DEA Response: DEA agreed with the recommendation and reported that its Diversion Control Division uses a number of programs and initiatives to identify new and emerging drug threats. Specifically, DEA stated that it uses the National Forensic Laboratory Information System (NFLIS), established in September 1997 and now called NFLIS-Drug, as a single data collection effort of drug chemistry analysis results from local, state, and federal forensic laboratories. In addition, DEA noted that these laboratories analyze substances recovered and seized in law enforcement operations across the country and monitor trafficking and illegal drug abuse, including the diversion of legally manufactured pharmaceutical drugs into illegal markets. Further, DEA reported that NFLIS-Drug includes data from forensic laboratories that conduct analyses of approximately 98 percent of the nation's annual drug cases and that as of February 2019 included 283 laboratories across the nation. DEA also stated that NFLIS-Drug data is used to support drug regulatory and scheduling efforts to inform drug policy and drug enforcement initiatives nationally and in local communities.

In addition, DEA stated that it recently expanded the NFLIS program to include (1) public and private toxicology laboratory data regarding postmortem and antemortem toxicological testing and (2) medical examiner and coroner office data regarding deaths in which drugs were identified. Moreover, DEA reported that it recently initiated a contract with the University of California at San Francisco whereby biological samples generated from overdose victims of synthetic drugs can be further analyzed. DEA stated that the goal of the program is to connect symptom causation and newly emerging synthetic drugs (i.e., synthetic cannabinoids, synthetic cathinones, fentanyl-related substances, other hallucinogens, etc.). The program will assist investigators in building "death resulting from" cases against those who traffic controlled substances.

OIG Analysis: DEA's actions are responsive to our recommendation. By January 3, 2020, please provide OIG with documentation supporting DEA's efforts to expand the NFLIS program to include public and private toxicology laboratory data regarding postmortem and antemortem toxicological testing and medical examiner and coroner office data regarding deaths in which drugs were identified. Also, please provide OIG with information regarding the quality and frequency with which these types of data will be entered into the NFLIS system, and how DEA will use this information to respond to emerging drugs threats.

APPENDIX 6

THE DEPARTMENT'S RESPONSE TO THE DRAFT REPORT

U.S. Department of Justice

Office of the Deputy Attorney General

Bradley Weinsheimer
Associate Deputy Attorney General

Washington, D.C. 20530

MEMORANDUM

TO: Nina S. Pelletier
Assistant Inspector General
Evaluation and Inspections Division
Office of the Inspector General

FROM: Bradley Weinsheimer
G. Bradley Weinsheimer
Associate Deputy Attorney General
Office of the Deputy Attorney General

DATE: September 25, 2019

SUBJECT: Response to OIG's Draft Report: "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, Assignment Number A-2017-003"

The Office of the Deputy Attorney General (ODAG) appreciates the review undertaken by the Office of the Inspector General (OIG) and the opportunity to comment on OIG's draft report, "Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, Assignment Number A-2017-003" (the "Report").

The Report sets forth several recommendations. Recommendations One through Eight are directed at the Drug Enforcement Administration (DEA). However, the Report also directs two separate recommendations for the Department below.

1. **Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs**

While the Department concurs with this recommendation, and will coordinate with DEA and state and local partners to effectuate it, we do wish to raise a few practical and legal concerns. As the OIG Report itself notes, state jurisdictions substantially limit law enforcement access to its Prescription Drug Monitoring Programs (PDMP). State authorities often require heightened legal cause (e.g. search warrant) to access PDMPs and sometimes prohibit access altogether. In jurisdictions that provide greater access to "state and local partners" than federal law enforcement, state law enforcement may not be able to share PDMP information with the DEA under state and local law.

Accordingly, we request that OIG's assessment of Department "efforts" recognize that it may not be feasible or legal for state law enforcement to afford DEA complete access to PDMPs in the manner contemplated by this recommendation.

2. **Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.**

The Department concurs with the recommendation. While the Department certainly will consider expanding the Opioid Fraud and Abuse Detection Unit pilot program upon its conclusion and will determine whether it would be feasible and appropriate to increase the number of federal prosecutors dedicated to prosecuting opioid-related cases, the allocation of limited prosecutorial resources is a matter reserved to the discretion of Department leadership. These decisions require policy determinations entailing careful cost and resource balancing of different strategic priorities and objectives.

APPENDIX 7

OIG ANALYSIS OF THE DEPARTMENT'S RESPONSE

OIG provided a draft of this report to the Office of the Deputy Attorney General (ODAG). ODAG's formal response is included in Appendix 6. ODAG concurred with all of OIG's recommendations. Below, we discuss OIG's analysis of ODAG's formal response and actions necessary to close the recommendations.

Recommendation 8: Make efforts to enlist state and local partners to provide DEA with consistent access to state-run Prescription Drug Monitoring Programs.

Status: Resolved.

ODAG Response: While the Department concurs with this recommendation and will coordinate with DEA and state and local partners to effectuate it, the Department wishes to raise a few practical and legal concerns. As the OIG report notes, state jurisdictions substantially limit law enforcement access to their Prescription Drug Monitoring Programs (PDMP). State authorities often require heightened legal cause (e.g., search warrants) to access PDMPs and sometimes prohibit access altogether. In jurisdictions that provide greater access to "state and local partners" than federal law enforcement, state law enforcement may not be able to share PDMP information with the DEA under state and local law.

Accordingly, we request that OIG's assessment of Department "efforts" recognize that it may not be feasible or legal for state law enforcement to afford DEA complete access to PDMPs in the manner contemplated by this recommendation.

OIG Analysis: ODAG's planned actions are responsive to our recommendation. OIG understands the limitations that the Department and DEA face in obtaining greater access to PDMP information. By January 3, 2020, please provide OIG with a status update regarding the efforts that the Department has made to enhance coordination between DEA and its state and local partners to obtain greater access to this information.

Recommendation 9: Consider expanding the Opioid Fraud and Abuse Detection Unit pilot to additional U.S. Attorney's Offices and increasing the number of federal prosecutors dedicated to prosecuting opioid-related cases.

Status: Resolved.

ODAG Response: The Department concurred with the recommendation. While the Department certainly will consider expanding the Opioid Fraud and Abuse Detection Unit pilot program upon its conclusion and will determine whether it would be feasible and appropriate to increase the number of federal prosecutors dedicated to prosecuting opioid-related cases, the allocation of limited prosecutorial resources is a matter reserved for the discretion of Department leadership. These decisions require policy determinations entailing careful cost and resource balancing of different strategic priorities and objectives.

OIG Analysis: ODAG's planned actions are responsive to our recommendation. By January 3, 2020, please provide OIG with a status update regarding any future plans for the maintenance and expansion of the Opioid Fraud and Abuse Detection Unit pilot program.

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